

Sanofi  
Form 20-F  
March 06, 2012  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 20-F**

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2011

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
Date of event requiring this shell company report . . . . .

For the transition period from            to

Commission File Number: 001-31368

**Sanofi**

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

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France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Senior Vice President Legal Affairs and General Counsel

54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
American Depositary Shares, each  representing one half of one ordinary share, par  value 2 per share	New York Stock Exchange
Ordinary shares, par value 2 per share	New York Stock Exchange  (for listing purposes only)
Contingent Value Rights	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

The number of outstanding shares of each of the issuer's classes of capital or  
common stock as of December 31, 2011 was:

Ordinary shares: 1,340,918,811

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405  
of the Securities Act.

YES  NO

If this report is an annual or transition report, indicate by check mark if the registrant is not  
required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

YES  NO

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP  International Financial Reporting Standards as issued by the International Accounting Standards Board  Other

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

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**PRESENTATION OF FINANCIAL AND OTHER INFORMATION**

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2011.

Unless the context requires otherwise, the terms Sanofi, the Company, the Group, we, our or us refer to Sanofi and its consolidated subsidiaries.

All references herein to United States or U.S. are to the United States of America, references to dollars or \$ are to the currency of the United States, references to France are to the Republic of France, and references to euro and € are to the currency of the European Union member states (including France) participating in the European Monetary Union.

Brand names appearing in this annual report are trademarks of Sanofi and/or its affiliates, with the exception of:

trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Actonel<sup>®</sup> trademark of Warner Chilcott; Avilomics a trademark of Avila Therapeutics Inc.; BiTE<sup>®</sup> a trademark of Micromet Inc., Copaxone<sup>®</sup> a trademark of Teva Pharmaceuticals Industries, Cortizone-10<sup>®</sup> a trademark of Johnson & Johnson (except in the United States where it is a trademark of the Group); Dynamic Electrochemistry<sup>®</sup> a trademark of AgaMatrix Inc.; epiCard (e-cue) a trademark of Intelliject; Gardasil<sup>®</sup> a trademark of Merck & Co.; Hyalgan<sup>®</sup> a trademark of Fidia Farmaceutici S.p.A, under license agreement in the United States; Leukine<sup>®</sup> a trademark of Alcaflu; Mutagrip<sup>®</sup> a trademark of Institut Pasteur; Optinate<sup>®</sup> a trademark of Warner Chilcott on certain geographical areas and of Shionogi Pharma Inc. in the United States; Pancréate a trademark of CureDM; Prevelle<sup>®</sup> a trademark of Mentor Worldwide LLC USA; RetinoStat<sup>®</sup> a trademark of Oxford Biomedica; and RotaTeq<sup>®</sup> a trademark of Merck & Co.;

trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace<sup>®</sup> a trademark of King Pharmaceuticals in the United States; Benzaclin<sup>®</sup> a trademark of Valeant in the United States and Canada, Carac<sup>®</sup> a trademark of Valeant in the United States; DDAVP<sup>®</sup> a trademark of Ferring (except in the United States where it is a trademark of the Group); Lactacyd<sup>®</sup> a trademark of GSK in certain countries; Liberty<sup>®</sup>, LibertyLink<sup>®</sup> and StarLink<sup>®</sup> trademarks of Bayer; Maalox<sup>®</sup> a trademark of Novartis in the United States, Canada and Puerto Rico; and Sculptra<sup>®</sup> a trademark of Valeant; and,

other third party trademarks such as Acrel<sup>®</sup> a trademark of Warner Chilcott; ACT<sup>®</sup> a trademark of Johnson & Johnson on certain geographical areas (except the United States and other countries where it is a trademark of Signal Investment); Aspirine<sup>®</sup>, Cipro<sup>®</sup>, Advantage<sup>®</sup> and Advantix<sup>®</sup> trademarks of Bayer; Eprinex<sup>®</sup> a trademark of Merck & Co. in certain countries; Humaneered a trademark of KaloBios Pharmaceuticals; IC31<sup>®</sup> a trademark of Intercell; iPhone<sup>®</sup> a trademark of Apple Inc.; LentiVector<sup>®</sup> and RetinoStat<sup>®</sup> trademarks of Oxford BioMedica; Libertas a trademark of Apotex in the United States and of International Contraceptive & SRH Marketing Limited in the United Kingdom; Mediator<sup>®</sup> a trademark of Biofarma; PetArmor<sup>®</sup> a trademark of Velcera, Inc.; Rotarix<sup>®</sup> a trademark of GSK; Sklice<sup>®</sup> a trademark of Topaz Pharmaceuticals LLC; Trajenta<sup>®</sup> a trademark of Boehringer Ingelheim; Unisom<sup>®</sup> a trademark of Johnson & Johnson on certain geographical areas (except the United States where it is a trademark of Signal Investment); and Xyzal<sup>®</sup> a trademark of GSK in certain countries and of UCB Farchim SA in some others.

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Not all trademarks related to investigational agents have been authorized as of the date of this annual report by the relevant health authorities; for instance Lyxumia® and Aubagio trade names have not been approved by the FDA.

The data relative to market shares and ranking information for pharmaceutical products presented in particular in Item 4. Information on the Company B. Business Overview Markets Marketing and distribution are based on sales data from IMS Health MIDAS (IMS), retail and hospital, for calendar year 2011, in constant euros (unless otherwise indicated).

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While we believe that the IMS sales data we present below are generally useful comparative indicators for our industry, they may not precisely match the sales figures published by the companies that sell the products (including our company and other pharmaceutical companies). In particular, the rules used by IMS to attribute the sales of a product covered by an alliance or license agreement do not always exactly match the rules of the agreement.

In order to allow a reconciliation with our basis of consolidation as defined in Item 5. Operating and Financial Review and Prospects Presentation of Net Sales, IMS data shown in the present document have been adjusted and include:

- (i) sales as published by IMS excluding Sanofi sales generated by the vaccines business, equating to the scope of our pharmaceutical operations;
- (ii) IMS sales of products sold under alliance or license agreements which we recognize in our consolidated net sales but which are not attributed to us in the reports published by IMS; and
- (iii) adjustments related to the exclusion of IMS sales for products which we do not recognize in our consolidated net sales but which are attributed to us by IMS.

Data relative to market shares and ranking information presented herein for our vaccines business are based on internal estimates unless stated otherwise.

Product indications described in this annual report are composite summaries of the major indications approved in the product's principal markets. Not all indications are necessarily available in each of the markets in which the products are approved. The summaries presented herein for the purpose of financial reporting do not substitute for careful consideration of the full labeling approved in each market.

## **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This annual report contains forward-looking statements. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

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projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;

statements of our profit forecasts, trends, plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and

statements about our future events and economic performance or that of France, the United States or any other countries in which we operate.

This information is based on data, assumptions and estimates considered as reasonable by the Company as at the date of this annual report and undue reliance should not be placed on such statements.

Words such as believe, anticipate, plan, expect, intend, target, estimate, project, predict, forecast, guideline, should and intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

Forward-looking statements involve inherent, known and unknown, risks and uncertainties associated with the regulatory, economic, financial and competitive environment, and other factors that could cause future results and objectives to differ materially from those expressed or implied in the forward-looking statements. The list below indicates some of the risk factors faced by the Company:

we rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected ;

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product liability claims could adversely affect our business, results of operations and financial condition ;

changes in the laws or regulations that apply to us could affect the Group's business, results of operations and financial condition ;

generic versions of some of our products may be approved for sale in one or more of their major markets ;

our long-term objectives may not be fully realized ;

we may fail to adequately renew our product portfolio whether through our own research and development or through acquisitions and strategic alliances ;

we may lose market share to competing remedies or generic brands if they are perceived to be equivalent or superior products ;

the diversification of the Group's business exposes us to additional risks ;

our products and manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals ;

we incurred substantial debt in connection with the acquisition of Genzyme which may limit our business flexibility compared to some of our peers ;

we face uncertainties over the pricing and reimbursement of pharmaceutical products ;

the ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business ;

the manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products ; and

risks related to financial markets.

We caution you that the foregoing list of risk factors is not exclusive and a number of important factors, discussed under Item 3. Key Information D. Risk Factors below, could affect the future results and cause actual results to differ materially from those contained in any forward-looking statements. Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.



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**PART I**

**Item 1. Identity of Directors, Senior Management and Advisers**

N/A

**Item 2. Offer Statistics and Expected Timetable**

N/A

**Item 3. Key Information**

***A. Selected Financial Data***

**SUMMARY OF SELECTED FINANCIAL DATA**

The tables below set forth selected consolidated financial data for Sanofi. These financial data are derived from the Sanofi consolidated financial statements. The Sanofi consolidated financial statements for the years ended December 31, 2011, 2010 and 2009 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2011, 2010 and 2009 have been prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2011. The term IFRS refers collectively to international accounting and financial reporting standards (IAS and IFRS) and to interpretations of the interpretations committees (SIC and IFRIC) mandatorily applicable as of December 31, 2011.

Sanofi reports its financial results in euros.

**Table of Contents****SELECTED CONDENSED FINANCIAL INFORMATION**

( million, except per share data)	As of and for the year ended December 31,				
	2011	2010	2009	2008	2007
<b>IFRS Income statement data<sup>(a)</sup></b>					
Net sales	33,389	32,367	29,785	27,568	28,052
Gross profit	24,156	24,638	23,125	21,480	21,636
Operating income	5,731	6,535	6,435	4,394	5,911
Net income attributable to equity holders of Sanofi	5,693	5,467	5,265	3,851	5,263
<b>Basic earnings per share ( \$)<sup>(b)</sup> :</b>					
Net income attributable to equity holders of Sanofi	4.31	4.19	4.03	2.94	3.91
<b>Diluted earnings per share ( \$)<sup>(c)</sup> :</b>					
Net income attributable to equity holders of Sanofi	4.29	4.18	4.03	2.94	3.89
<b>IFRS Balance sheet data</b>					
Goodwill and other intangible assets	61,718	44,411	43,480	43,423	46,381
Total assets	100,165	85,264	80,251	71,987	71,914
Outstanding share capital	2,647	2,610	2,618	2,611	2,657
Equity attributable to equity holders of Sanofi	56,219	53,097	48,322	44,866	44,542
Long term debt	12,499	6,695	5,961	4,173	3,734
Cash dividend paid per share ( \$) <sup>(d)</sup>	2.65 <sup>(e)</sup>	2.50	2.40	2.20	2.07
Cash dividend paid per share ( \$) <sup>(d)(f)</sup>	3.43 <sup>(e)</sup>	3.34	3.46	3.06	3.02

<sup>(a)</sup> The results of operations of Merial, for 2010 and 2009, previously reported as held-for-exchange, have been reclassified and included in net income of continuing in accordance with IFRS 5.36., following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separate businesses operating independently.

<sup>(b)</sup> Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,321.7 million shares in 2011, 1,305.3 million shares in 2010, 1,305.9 million shares in 2009, 1,309.3 million shares in 2008, and 1,346.9 million shares in 2007.

<sup>(c)</sup> Based on the weighted average in each period of the number of shares outstanding plus stock options and restricted shares with a potentially dilutive effect; i.e., 1,326.7 million shares in 2011, 1,308.2 million shares in 2010, 1,307.4 million shares in 2009, 1,310.9 million shares in 2008, and 1,353.9 million shares in 2007.

<sup>(d)</sup> Each American Depositary Share, or ADS, represents one half of one share.

<sup>(e)</sup> Dividends for 2011 will be proposed for approval at the annual general meeting scheduled for May 4, 2012.

<sup>(f)</sup> Based on the relevant year-end exchange rate.

**Table of Contents****SELECTED EXCHANGE RATE INFORMATION**

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2007 through March 2012 expressed in U.S. dollars per euro. The information concerning the U.S. dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate). We provide the exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into U.S. dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5. Operating and Financial Review and Prospects and Item 11. Quantitative and Qualitative Disclosures about Market Risk.

	<b>Period- end Rate</b>	<b>Average Rate <sup>(1)</sup> (U.S. dollar per euro)</b>	<b>High</b>	<b>Low</b>
2007	1.46	1.38	1.49	1.29
2008	1.39	1.47	1.60	1.24
2009	1.43	1.40	1.51	1.25
2010	1.33	1.32	1.45	1.20
2011	1.30	1.40	1.49	1.29
Last 6 months				
2011				
September	1.34	1.37	1.43	1.34
October	1.39	1.37	1.42	1.33
November	1.35	1.36	1.38	1.32
December	1.30	1.32	1.35	1.29
2012				
January	1.31	1.29	1.32	1.27
February	1.34	1.32	1.35	1.31
March <sup>(2)</sup>	1.32	1.32	1.33	1.32

<sup>(1)</sup> The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being February 24, 2012, we have used European Central Bank Rates for the period from February 27, 2012 till February 29, 2012.

<sup>(2)</sup> In each case, measured through March 5, 2012.

On March 5, 2012 the European Central Bank Rate was 1.3220 per euro.

**B. Capitalization and Indebtedness**

N/A

**C. Reasons for Offer and Use of Proceeds**

N/A

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### ***D. Risk Factors***

*Important factors that could cause actual financial, business, research or operating results to differ materially from expectations are disclosed in this annual report, including without limitation the following risk factors and the factors described under **Cautionary Statement Regarding Forward-Looking Statements**. In addition to the risks listed below, we may be subject to other material risks that as of the date of this report are not currently known to us or that we deem immaterial at this time.*

### **Risks Relating to Legal Matters**

**We rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected.**

Through patent and other proprietary rights such as supplementary protection certificate in Europe for instance, we hold exclusivity rights for a number of our research-based products. However, the protection that we are able to obtain varies from product to product and country to country and may not be sufficient to maintain effective product exclusivity because of local variations in the patents, differences in national law or legal systems, development in law or jurisprudence, or inconsistent judgments. We are involved in litigation worldwide to enforce certain of these patent rights against generics and proposed generics (see **Item 8. Financial Information – A. Consolidated Financial Statements and Other Financial Information – Information on Legal or Arbitration Proceedings** for additional information). Moreover, patent rights are limited in time and do not always provide effective protection for our products: competitors may successfully avoid patents through design innovation, we may not hold sufficient evidence of infringement to bring suit, or our infringement claim may not result in a decision that our rights are valid, enforceable or infringed. Moreover, a number of countries are increasingly easing the introduction of generic drugs or biosimilar products through accelerated approval procedures.

Even in cases where we ultimately prevail in our infringement claim, legal remedies available for harm caused to us by infringing products may be inadequate to make us whole. A competitor may launch a generic product **at risk** before the initiation or completion of the court proceedings, and the court may decline to grant us a preliminary injunction to halt further **at risk** sales and remove the infringing product from the market. Additionally, while we would be entitled to obtain damages in such a case, the amount that we may ultimately be awarded and able to collect may be insufficient to compensate all harm caused to us.

Further, our successful assertion of a given patent against one competing product is not necessarily predictive of our future success or failure in asserting the same patent against a second competing product because of such factors as possible differences in the formulations. Also a successful result in one country may not predict success in another country because of local variations in the patents.

To the extent valid third-party patent rights cover our products, we or our partners may be required to obtain licenses from the holders of these patents in order to manufacture, use or sell these products, and payments under these licenses may reduce our profits from these products. We may not be able to obtain these licenses on favorable terms, or at all. If we fail to obtain a required license or are unable to alter the design of our technology to fall outside the scope of a third-party patent, we may be unable to market some of our products, which may limit our profitability.

**Product liability claims could adversely affect our business, results of operations and financial condition.**

Product liability is a significant business risk for any pharmaceutical company, and the Group's ongoing diversification could increase our product liability exposure (see notably The diversification of the Group's business exposes us to additional risks below). Substantial damage awards and/or settlements have been made notably in the United States and other common law jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of their products. Such claims can also be accompanied by consumer fraud claims by customers or third-party payers seeking reimbursement of the cost of the product. Often the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical studies involving only several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety surveillance and clinical trials provide additional information for example, potential evidence of rare, population-specific or long-term adverse reactions or of drug



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interactions that were not observed in preapproval clinical studies and may cause product labeling to evolve, including restrictions of therapeutic indications, new contraindications, warnings or precautions, and occasionally even the suspension or withdrawal of a product marketing authorization. Several pharmaceutical companies have withdrawn products from the market because of newly detected or suspected adverse reactions to their products, and as a result of such withdrawal now face significant product liability claims. We are currently defending a number of product liability claims (see Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report) and there can be no assurance that the Group will be successful in defending against each of these claims or will not face additional claims in the future. Also our risk exposure also increased due to the fact that we are now commercializing some devices using new technologies which, in case of malfunction, could cause unexpected damages and trigger our liability (see We are increasingly dependent on information technologies and networks. below).

Although we continue to insure a portion of our product liability with third-party carriers, product liability coverage is increasingly difficult and costly to obtain, particularly in the United States, and in the future it is possible that self-insurance may become the sole commercially reasonable means available for managing the product liability financial risk of our pharmaceutical and vaccines businesses (see Item 4. Information on the Company B. Business Overview Insurance and Risk Coverage ). Due to insurance conditions, even when the Group has insurance coverage, recoveries from insurers may not be totally successful. Moreover the insolvency of a carrier could negatively affect our ability to achieve the practical recovery of the coverage for which we have already paid a premium.

Product liability claims, regardless of their merits or the ultimate success of the Group's defense, are costly, divert management attention, may harm our reputation and can impact the demand for our products. Substantial product liability claims, if successful, could adversely affect our business, results of operations and financial condition.

**Claims and investigations relating to competition law, marketing practices and pricing could adversely affect our business, results of operations and financial condition.**

The marketing of our products is heavily regulated, and alleged failures to comply fully with applicable regulations could subject us to substantial fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs. Sanofi and certain of its subsidiaries are under investigation by various government entities and are defending a number of lawsuits relating to antitrust and/or pricing and marketing practices, including, for example in the United States, class action lawsuits and whistle blower litigation. See Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

Because many of these cases allege substantial unquantified damages, may be subject to treble damages and frequently seek significant punitive damages and penalties, it is possible that any final determination of liability or settlement of these claims or investigations could have a material adverse effect on our business, results of operations or financial condition.

**There are other legal matters in which adverse outcomes could have a material adverse effect on our business, results of operations and financial condition.**

The Group faces significant litigation and government investigations or audits, including allegations of securities law violations, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits.

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Unfavorable outcomes in these matters, or in similar matters to be faced in the future, could preclude the commercialization of products, negatively affect the profitability of existing products and subject us to substantial fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs. Any such result could materially and adversely affect our results of operations, financial condition, or business. See Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings and Note D.22. to our consolidated financial statements included at Item 18 of this annual report.

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**Changes in the laws or regulations that apply to us could affect the Group's business, results of operations and financial condition.**

Governmental authorities are increasingly looking to facilitate generic and biosimilar competition to existing products through new regulatory proposals intended to, or resulting in, changes to the scope of patent or data exclusivity rights and use of accelerated regulatory pathways for generic and biosimilar drug approvals. Such regulatory proposals, if enacted, could make prosecution of patents for new products more difficult and time consuming or could adversely affect the exclusivity period for our products, thereby materially and adversely affecting our financial results.

This new competitive environment and potential regulatory changes may further limit the exclusivity enjoyed by innovative products on the market and directly impact pricing and reimbursement levels, which may adversely affect our business and future results. See Item 4. Information on the Company B. Business Overview Competition and Item 4. Information on the Company B. Business Overview Regulation .

In addition, changes in tax laws or in their application with respect to matters such as tax rates, transfer pricing, dividends, controlled companies or a restriction in certain forms of tax relief, could affect our effective tax rate and our future results.

For information regarding risks related to changes in environmental rules and regulations, see Environmental liabilities and compliance costs may have a significant adverse effect on our results of operations below.

**Risks Relating to Our Business**

**Generic versions of some of our products may be approved for sale in one or more of their major markets.**

Many of our products are subject to aggressive generic competition, and additional products of the Group could become subject to generic competition in the future as product patents and/or exclusivities for several of our products have recently expired, or are about to expire. For example pediatric exclusivity for Aprovel<sup>®</sup> and Plavix<sup>®</sup> which contribute significantly to our net income will expire in the United States in March 2012 and May 2012, respectively, and the compound patent of Aprovel<sup>®</sup> will expire in most of the European Union in August 2012. Also, the U.S. market exclusivity of Eloxatin<sup>®</sup> will expire in August 2012, pursuant to settlement agreements. We expect this generic competition to continue and to implicate drug products with even relatively modest revenues.

The introduction of a generic version of a branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at sharply lower prices. Accordingly, approval and market entry of a generic product often reduces the price that we receive for these products and/or the volume of the product that we would be able to sell and could materially and adversely affect our business, results of operations and financial condition. The extent of sales erosion also depends on the number of generic versions of our products that are actually marketed. For instance in 2011, there was only one generic product of enoxaparin sodium (Lovenox<sup>®</sup>) marketed in the United States. The introduction of a second generic on the U.S. market in early 2012 is likely to decrease our sales and revenues on this product.

**Our long-term objectives may not be fully realized.**

We have established a strategy focused on three pillars: increased innovation in R&D, adaptation of our structure for future opportunities and challenges and pursuit of external growth opportunities. We may not be able to fully realize our strategic objectives and, even if we are able to do so, these strategic objectives may not deliver the expected benefits.

For example, our strategy involves concentrating efforts around identified growth platforms and meeting significant growth objectives over 2012-2015. There is no guarantee that we will meet these objectives or that these platforms will grow in line with anticipated growth rates. A failure to continue to expand our business in targeted growth platforms could affect our business, results of operations or financial condition.

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As a further example, we are implementing a cost savings program across the Group and expect this new initiative, together with expected synergies from our recent acquisition of Genzyme, to generate additional incremental cost savings by 2015. We may fail to realize all the expected cost savings, which could materially and adversely affect our financial results.

### **We may fail to adequately renew our product portfolio whether through our own research and development or through acquisitions and strategic alliances.**

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to take the place of products facing expiration of patent and regulatory data exclusivity or competition from new products that are perceived as being superior. In 2011, we spent 4,811 million on research and development, amounting to approximately 14.4% of our net sales.

Developing a product is a costly, lengthy and uncertain process. Also we may not be investing in the right technology platforms, leading therapeutic area, and products classes in order to build a robust pipeline and fulfill unmet medical needs. Fields of discovery and especially biotechnology are highly competitive and characterized by significant and rapid technological changes. Numerous companies are working on the same targets and a product considered as promising at the very beginning may become less attractive if a competitor showing the same mechanism of action reaches earlier the market.

The research and development process typically takes from 10 to 15 years from discovery to commercial product launch. This process is conducted in various stages in order to test, along with other features, the effectiveness and safety of a product. There can be no assurance that any of these compounds will be proven safe or effective. See Item 4. Information on the Company B. Business Overview Pharmaceutical Research & Development and Item 4. Information on the Company B. Business Overview Vaccines Research and Development . Accordingly, there is a substantial risk at each stage of development that we will not achieve our goals of safety and/or effectiveness including during the course of a development trial and that we will have to abandon a product in which we have invested substantial amounts and human resources, including in late stage development (Phase III). Decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given product. Multiple in-depth studies can demonstrate that a product has additional benefits, facilitating the product's marketing, but such studies are expensive and time consuming and may delay the product's submission to health authorities for approval.

Our ongoing investments in new product launches and research and development for future products could therefore result in increased costs without a proportionate increase in revenues which may negatively affect our operating results. Each regulatory authority may also impose its own requirements in order to grant a license to market the product, including requiring local clinical studies, and may delay or refuse to grant approval, even though a product has already been approved in another country. Finally, obtaining regulatory marketing approval is not a guarantee that the product will achieve commercial success. Following each product marketing approval, the medical need served by the product and the corresponding reimbursement rate are evaluated by other governmental agencies which may in some cases require additional studies, including comparative studies, which may both effectively delay marketing of the new product and add to its development costs.

Also our success depends on our ability to educate patients and healthcare providers and provide them with innovative data about our products and their uses. If these education efforts are not effective, then we may not be able to increase the sales of our new products to the market.

On the same topic, for the research and development of drugs in rare diseases, we produce relatively small amounts of material at early stages. Even if a product candidate receives all necessary approvals for commercialization, we may not be able to successfully scale-up production of the product material at a reasonable cost or at all and we may not receive additional approvals in sufficient time to meet product demand.

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As a complement to our portfolio of products, we pursue a strategy of selective acquisitions, in-licensing and partnerships in order to develop new growth opportunities. The implementation of this strategy depends on our ability to identify business development opportunities at a reasonable cost and under acceptable conditions of

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financing. Moreover, entering into these in-licensing or partnership agreements generally requires the payment of significant milestones well before the relevant products are placed on the market without any assurance that such investments will ultimately become profitable in the long term.

Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

### **A substantial share of the revenue and income of the Group continues to depend on the performance of certain flagship products.**

We generate a substantial share of our revenues from the sale of certain key products (see Item 5. Operating and Financial Review and Prospects Results of Operations Year ended December 31, 2011 compared with year ended December 31, 2010 Net Sales by Product Pharmaceuticals ), which represented 37.6% of the Group's consolidated revenues in 2011. Among these products is Lantus®, which was the Group's leading product with revenues of 3,916 million in 2011, representing 11.7% of the Group's consolidated revenues for the year. Lantus is a flagship product of the Diabetes division, one of the Group's growth platforms.

Sales of Cerezyme®, our enzyme-replacement product for patients with Gaucher disease which is also amongst our flagship products, totaled 441 million for the year ended December 31, 2011, below the usual level of sales due to important production disruptions since 2009 (see The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products. below). In addition the patient population with Gaucher disease is limited. Furthermore, changes in the methods for treating patients with such disease could limit growth, or result in a decline, in Cerezyme® sales.

In general, a reduction in sales of one or more of our flagship products or in their growth could affect our business, results of operations and financial condition.

### **We may lose market share to competing remedies or generic brands if they are perceived to be equivalent or superior products.**

We are faced with intense competition from generic products and brand-name drugs. Doctors or patients may choose these products over ours if they perceive them to be safer, more reliable, more effective, easier to administer or less expensive, which could cause our revenues to decline and affect our results of operations.

For example, Cerezyme® and Fabrazyme® shortages due to manufacturing issues at our facility in Allston, Massachusetts (United-States) (see The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products. below) created, and continue to create, opportunities for our competitors and have resulted in a decrease in the number of patients using these products and a loss of our overall market share of Gaucher and Fabry patients, respectively. Even if we are able again to provide a full, sustainable product supply, there is no guarantee these patients will return to using our products.

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Additionally, the market for our products could also be affected if a competitor's innovative drug in the same market were to become available as generic because a certain number of patients can be expected to switch to a lower-cost alternative therapy.

### **The diversification of the Group's business exposes us to additional risks.**

We are implementing a strategy that includes pursuing external growth opportunities to meet the challenges that we have identified for the future. The inability to quickly or efficiently integrate newly acquired activities or businesses, such as Genzyme, the loss of key employees or integration costs that are higher than anticipated, could delay our growth objectives and prevent us from achieving expected synergies. For instance, challenges that we may face in our efforts to integrate Genzyme include, among others:

addressing manufacturing problems and supply constraints that have negatively affected Genzyme's business in recent years;



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ensuring continued compliance with a consent decree that Genzyme entered into with the FDA in May 2010 relating to a manufacturing facility in Allston, Massachusetts (United-States) (see Item 4. Information on the Company B. Business Overview Production and Raw Materials. );

the outcome of ongoing legal and other proceedings to which Genzyme is a party, including shareholder litigation and patent litigation;

preserving and developing Genzyme's goodwill in the genetic disease community; and

realizing the potential of the research and development pipeline.

If we fail to effectively integrate Genzyme or the integration takes longer than expected, we may not achieve the expected benefits of the transaction.

Moreover, we may miscalculate the risks associated with newly acquired activities or businesses at the time they are acquired or not have the means to evaluate them properly. It may take a considerable amount of time and be difficult to implement a risk analysis after the acquisition is completed due to lack of historical data. As a result, risk management and the coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

While pursuing our objective to become a global and diversified leader within the health industry, we are exposed to a number of new risks inherent in sectors in which, in the past, we have been either less active or not present at all. As an example:

we have increased exposure to the animal health business. The contribution of our animal health business to the Group's income may be adversely affected by a number of risks including some which are specific to this business: *i.e.*, the outbreak of an epidemic or pandemic that could kill large numbers of animals, and the effect of reduced veterinary expenditures during an economic crisis (see The ongoing slowdown of global economic growth and the global financial crisis could have negative consequences for our business below).

the margins of consumer health and generic products are generally lower than those of the traditional branded prescription pharmaceutical business. Moreover, the periodic review of the effectiveness, safety and use of certain over-the-counter drug products by health authorities or lawmakers may result in modifications to the regulations that apply to certain components of such products, which may require them be withdrawn from the market and/or that their formulation be modified.

specialty products (such as those developed by Genzyme) that treat rare, life-threatening diseases that are used by a small number of patients are often expensive to develop compared to the market opportunity, and third-party payers trying to limit health-care expenses may become less willing to support their per-unit cost.

Moreover, losses that may be sustained or caused by these new businesses may differ, with regards to their nature, scope and level, from the types of product liability claims that we have handled in the past (see Product liability claims could adversely affect our business, results of operations and financial condition above), and thus our current risk management and insurance coverage may not be adapted to such losses. These risks could affect our business, results of operations or financial condition.

**The globalization of the Group's business exposes us to increased risks.**

Emerging markets have been identified as one of our growth platforms and are among the pillars of our overall strategy. Any difficulties in adapting to emerging markets and/or a significant decline in the anticipated growth rate in these regions could impair our ability to take advantage of these growth opportunities and could affect our business, results of operations or financial condition.

There is no guarantee that our efforts to expand sales in emerging markets will succeed. The significant expansion of our activities in emerging markets may further expose us to more volatile economic conditions, political instability, competition from companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of these markets, particularly with respect to their regulatory frameworks, difficulties in recruiting qualified personnel, potential exchange controls, weaker intellectual

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property protection, higher crime levels (particularly with respect to counterfeit products (see Counterfeit versions of our products harm our business, below)), corruption and fraud, as we operate in many parts of the world where corruption exists to some degree.

Our existing policies and procedures, which are designed to help ensure that we, our employees and our agents comply with the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, and other anti-bribery laws, may not adequately protect us against liability under these laws for actions taken by our employees, agents and intermediaries with respect to our business. Failure to comply with domestic or international laws could result in various adverse consequences, including possible delay in the approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, or the imposition of criminal or civil sanctions, including substantial monetary penalties.

**Our products and manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals.**

The industry in which we operate faces a changing regulatory environment and heightened public scrutiny worldwide, which simultaneously require greater assurances than ever as to the safety and efficacy of medications and health products on the one hand, and effectively provide reduced incentives for innovative pharmaceutical research on the other hand.

Health authorities, are increasingly focusing on product safety and on the risk/benefit profile of pharmaceuticals products. In particular, the FDA and the European Medicines Agency (EMA) have imposed increasingly burdensome requirements on pharmaceutical companies, particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety. For the same reasons, the marketed products are subject to continual review, risk evaluations or comparative effectiveness studies even after regulatory approval. These requirements have resulted in increasing the costs associated with maintaining regulatory approvals and achieving reimbursement for our products.

Later discovery of previously undetected problems may result in marketing restrictions or the suspension or withdrawal of the product, as well as an increased risk of litigation for both pharmaceutical and animal health products. These post-regulatory approval reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient organizations or other specialized organizations regarding the use of products, which may result in a reduction in sales volume, such as, for example, a recommendation to limit the patient scope of a drug's indication. For instance in September 2011, the EMA defined a more restrictive indication for Multaq, one of our cardiovascular products. Such reviews may result in the discovery of significant problems with respect to a competing product that is similar to one sold by the Group, which may in turn cast suspicion on the entire class to which these products belong and ultimately diminish the sales of the relevant product of the Group. When such issues arise, the contemplative nature of evidence-based health care and restrictions on what pharmaceutical manufacturers may say about their products are not always well suited to rapidly defending the Group or the public's legitimate interests in the face of the political and market pressures generated by social media and rapid news cycles, and this may result in unnecessary commercial harm, overly restrictive regulatory actions and erratic share price performance.

In addition, to the extent that new regulations raise the costs of obtaining and maintaining product authorization, or limit the economic value of a new product to its inventor, the growth prospects of our industry and of the Group are diminished. Also about 50% of our current research and development portfolio is constituted by biological products, that may bring in the future new therapeutic responses to current unmet medical needs but which may also lead to more technical constraints and costly investments from an industrial standpoint.

Moreover, we and certain of our third-party suppliers are also required to comply with applicable regulations, known as good manufacturing practices, which govern the manufacture of pharmaceutical products. To monitor our compliance with those applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies which

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might be expensive and time consuming to address. If we fail to adequately respond to a warning letter

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identifying a deficiency, or otherwise fail to comply with applicable regulatory requirements, we could be subject to enforcement, remedial and/or punitive actions by the FDA, the EMA or other regulatory authorities.

For example, in May 2010, Genzyme entered into a consent decree with the FDA relating to its Allston facility (see Item 4. Information on the Company B. Business Overview Production and Raw Materials. ). Pursuant to the consent decree, in November 2010, Genzyme paid \$175.0 million to the U.S. Federal Government disgorgement of past profits. The consent decree also requires Genzyme to implement a plan to bring the Allston facility into compliance with applicable laws and regulations. Genzyme submitted a comprehensive remediation plan to FDA in April 2011. Remediation of the Allston facility in accordance with that plan is underway and is currently expected to continue for four more years, however, there is no guarantee that this timeframe will be respected.

### **We incurred substantial debt in connection with the acquisition of Genzyme which may limit our business flexibility compared to some of our peers**

Our consolidated debt increased substantially in connection with our acquisition of Genzyme because we incurred debt to finance the acquisition price, and because our consolidated debt includes the debt incurred by Genzyme prior to the acquisition. Although we already achieved a partial deleverage by the end of 2011 (as of December 31, 2011, our debt, net of cash and cash equivalents amounted to 10.9 billion), we make significant debt service payments to our lenders and this could limit our ability to engage in new transactions which could have been part of our strategy.

### **We face uncertainties over the pricing and reimbursement of pharmaceutical products.**

The commercial success of our existing products and our products candidates depends in part on the conditions under which our products are reimbursed. Pressure on pricing and reimbursement is strong due to:

price controls imposed by governments in many countries;

removal of a number of drugs from government reimbursement schemes (for instance products determined to be less cost-effective than alternatives);

increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates; and

the tendency of governments and private health care providers to favor generic pharmaceuticals.

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products. In the United States, health care reform law is increasing the government's role with respect to price, reimbursement and the coverage levels for healthcare-related expenses for the large government health care sector, imposed cost containment measures and imposed drug companies rebates to the government. Implementation of health care reform has affected and could still affect our revenues and/or margins (for further details concerning this law and a description of certain regulatory pricing systems that affect our Group see Item 4. Information on the Company

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B. Business Overview Pricing & Reimbursement ). Some states are also considering legislation that would control the prices of and access to drugs and we believe that federal and state legislatures and health agencies will continue to focus on healthcare reform implementation in the future.

We encounter similar cost containment issues in countries outside the United States. In certain countries, including countries in the EU and Canada, the coverage of prescription drugs, pricing and levels of reimbursement are subject to governmental control. For example, in Spain, recent direct price-related measures include price discount to all products launched more than 10 years ago, all genericized products needing to be at a minor (lower) price, and no more gradualism in price reductions of originator post generics introduction. Additionally, measures such as INN prescriptions, have been implemented. Another example, in Turkey Government has accelerated enforcement of drugs costs containment measures which include increased institutional discount applied on reimbursement prices and lower reference prices for reimbursement of Generics and originals with Generics as well as 20-year old drugs without Generics.

Due to the ongoing cost containment policies being pursued in many jurisdiction in which we operate, we are unable to predict the availability or amount of reimbursement for our product candidates.

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In addition, our operating results may also be affected by parallel imports, particularly within the European Union, whereby distributors engage in arbitrage based on national price differences to buy product on low cost markets for resale on higher cost markets.

### **The ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business<sup>1</sup>.**

Over the past several years, growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and lasting slowdown of the global economy or major national economies could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business. This effect may be expected to be particularly strong in markets having significant co-pays or lacking a developed third-party payer system, as individual patients may delay or decrease out-of-pocket healthcare expenditures. Such a slowdown could also reduce the sources of funding for national social security systems, leading to heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies.

Additionally, to the extent the slowing economic environment, as well as ongoing sovereign debt crisis affecting several European countries, may lead to financial difficulties or even the default or failure of major players including wholesalers or public sector buyers financed by insolvent States, the Group could experience disruptions in the distribution of its products as well as the adverse effects described below at We are subject to the risk of non-payment by our customers . Moreover, to the extent that the economic and financial crisis is directly affecting business, it may also lead to a disruption or delay in the performance of third parties on which we rely for parts of our business, including collaboration partners and suppliers (for more information see Item 5. Operating and Financial Review and Prospects Liquidity. ). Such disruptions or delays could have a material and adverse effect on our business and results of operations. See We rely on third parties for the manufacture and supply of a substantial portion of our raw materials, active ingredients and medical devices; supply disruptions and/or quality concerns could adversely affect our operating results and financial condition , We rely on third parties for the marketing of some of our products and Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition below.

Further, we believe our net sales may be negatively impacted by the continuing challenging global economic environment, as high unemployment levels and increases in co-pays may lead some patients to switch to generic products, delay treatments, skip doses or use less effective treatments to reduce their costs. Moreover, current economic conditions in the United States have resulted in an increase in the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many U.S. states, to formulary restrictions limiting access to brand-name drugs, including ours.

Our animal health business may also be negatively affected by the current slowdown in global economic growth (for instance tight credit conditions may limit the borrowing power of livestock producers, causing some to switch to lower-priced products).

### **The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products.**

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. We must also be able to produce sufficient quantities of the products to satisfy demand. Our biologic products (including vaccines) in particular are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent to the processing of biological materials and the potential unavailability of adequate amounts of raw materials meeting our standards. Additionally, specific conditions must be respected both by the Group and our customers for the storage and distribution of many of our products, e.g., cold storage for certain vaccines and insulin-based products. The complexity of these processes, as well as strict internal and government standards for the manufacture of our products, subject us to risks. The occurrence or suspected occurrence of out-of-specification

<sup>1</sup> Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with respect to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements.



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production or storage can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability (see Product liability claims could adversely affect our business, results of operations and financial condition, above). The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and the delay of new product launches and can adversely affect our operating results and financial condition.

Like many of our competitors, we have faced, and to a certain extent continue to face, significant manufacturing issues, most notably in our Genzyme subsidiary for the production of Cerezyme® and Fabrazyme®. In June 2009, Genzyme announced it had detected a virus that impairs cell growth in one of the bioreactors used in the Allston, Massachusetts facility to produce Cerezyme®. This contamination has had a material adverse effect on Cerezyme® and Fabrazyme® revenues. We will continue to work with minimal levels of inventory for Cerezyme® and Fabrazyme® until we are able to build inventory. However, there can be no guarantee that we will be able to return to pre-contamination supply levels of such products, nor can there be any guarantee that we will not face similar issues in the future or that we will successfully manage such issues when they arise.

### **We rely on third parties for the manufacture and supply of a substantial portion of our raw materials, active ingredients and medical devices; supply disruptions and/or quality concerns could adversely affect our operating results and financial condition.**

Third parties supply us with a substantial portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply interruption in the event that these suppliers experience financial difficulties or are unable to manufacture a sufficient supply of our products meeting Group quality standards. It also increases the risk of quality issues, even with the most scrupulously selected suppliers.

If disruptions or quality concerns were to arise in the third-party supply of raw materials, active ingredients or medical devices, this could adversely affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products above. We may not have redundant manufacturing capacity for certain products particularly biologic products. For instance in summer 2011 a technical incident occurred in the filling line used for Apidra 3mL cartridges at our manufacturing site in Frankfurt and this has caused temporary shortages for Apidra 3mL cartridges. Also all of our bulk Cerezyme® products are produced solely at our Allston, Massachusetts facility. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at a second or third facility when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Switching sources and manufacturing facilities may require significant time.

Further, some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox®. Heparin purchase prices can also fluctuate. See Item 4. Information on the Company B. Business Overview Production and Raw Materials for a description of these outsourcing arrangements. Any of these factors could adversely affect our business, operating results or financial condition.

### **We rely on third parties for the marketing of some of our products.**

We market some of our products in collaboration with other pharmaceutical companies. For example, we currently have major collaborative arrangements with Bristol-Myers Squibb (BMS) for the marketing of Plavix® and Aprovel® in the United States and several other countries, with Warner Chilcott for the osteoporosis treatment Actonel®, and with Merck & Co., Inc. for the distribution of vaccines in Europe. See Item 4. Information on the Company B. Business Overview Pharmaceutical Products Main pharmaceutical products and Item 4. Information on the

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Company B. Business Overview Vaccine Products for more information on our major alliances. When we market our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with BMS are subject to the operational management of BMS in some countries, including the United States. Any conflicts that

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we may have with our partners during the course of these agreements or at the time of their renewal or renegotiation may affect the marketing of certain of our products and may cause a decline in our revenues and affect our results of operations.

### **Counterfeit versions of our products harm our business.**

The drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as Sanofi. Additionally, it is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. If a Group product was the subject of counterfeits, the Group could incur substantial reputational and financial harm. See Item 4. Information on the Company B. Business Overview Competition.

### **We are subject to the risk of non-payment by our customers.<sup>1</sup>**

We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. This risk is accentuated by the current worldwide financial crisis. The United States poses particular client credit risk issues, because of the concentrated distribution system in which approximately 62% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. In addition, the Group's three main customers represent 17.4% of our gross total revenues. We are also exposed to large wholesalers in other markets, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to us could adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18 of this annual report).

Since the beginning of 2010, financial difficulties in some countries of southern Europe have increased especially in Greece and Portugal. Part of our customers in these countries are public or subsidized health systems. The deteriorating economic and credit conditions in these countries has led to longer payment terms. This trend may continue and we may need to reassess the recoverable amount of our debts in these countries during the coming financial years (for more information see Item 5. Operating and Financial Review and Prospects Liquidity. ).

### **Our pension liabilities are affected by factors such as the performance of plan assets, interest rates, actuarial data and experience and changes in laws and regulations.**

Our future funding obligations for our main defined-benefit pension plans depend on changes in the future performance of assets held in trust for these plans, the interest rates used to determine funding levels (or company liabilities), actuarial data and experience, inflation trends, the level of benefits provided for by the plans, as well as changes in laws and regulations. Adverse changes in those factors could increase our unfunded obligations under such plans, which would require more funds to be contributed and hence negatively affect our cash flow and results (see Note D.19.1 to our consolidated financial statements included at Item 18 of this annual report).

### **Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Group's results of operations and financial results.**

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New or revised accounting standards, rules and interpretations issued from time to time by the IASB (International Accounting Standards Board) could result in changes to the recognition of income and expense that may materially and adversely affect the Group's financial results.

- 1 Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with respect to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements and by Notes D.10. and D.34. to our consolidated financial statements included at Item 18 of this annual report.

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In addition, substantial value is allocated to intangible assets and goodwill resulting from business combinations, as disclosed at Note D.4. to our consolidated financial statements included in this annual report at Item 18, which could be substantially impaired upon indications of impairment (primarily relating to pharmacovigilance, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

Also if any of our strategic equity investments decline in value and remain below cost for an extended duration, we may be required to write down our investment.

In addition the global financial crisis and in particular the ongoing sovereign debt crisis affecting certain European countries could also negatively affect the value of our assets (see Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition below and The ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business above). For example, given the current level of investor confidence in the ability of the Greek State to avoid default, as a result of mark to market accounting standards, we recognized an impairment of 49 million on certain Greek bonds held by us in 2011.

### **We are increasingly dependent on information technologies and networks.**

Our business depends on the use of information technologies, which means that certain key areas such as research and development, production and sales are to a large extent dependent on our information technology capabilities. We are commercializing some devices using new technologies which, in case of malfunctions could lead to a misuse causing a risk of damages to patients (see Product liability claims could adversely affect our business, results of operations and financial condition above). Our inability or the inability of our third-party service providers (for instance the accounting of some of our subsidiaries has been externalized) to implement adequate security and quality measures for data processing could lead to data deterioration or loss in the event of a system malfunction, or allow data to be stolen or corrupted in the event of a security breach, which could have a material adverse effect on our business, operating results and financial condition.

### **Natural disasters prevalent in certain regions in which we do business could affect our operations**

Some of our production sites are located in areas exposed to natural disasters, such as earthquakes (in North Africa, Middle East, Asia, Pacific, Europe, Central and Latin Americas), floods (in Africa, Asia Pacific and Europe) and hurricanes. In the event of a major disaster we could experience severe destruction or interruption of our operations and production capacity. As a result, our operations could suffer serious harm which could have a material adverse effect on our business, financial condition and results of operations.

### **Environmental Risks of Our Industrial Activities**

#### **Risks from the handling of hazardous materials could adversely affect our results of operations.**

Manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and wastes, expose us to various risks, including:

fires and/or explosions;

storage tank leaks and ruptures; and

discharges or releases of toxic or hazardous substances.

These operating risks can cause personal injury, property damage and environmental contamination, and may result in:

the shutdown of affected facilities; and

the imposition of civil or criminal penalties.

The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

Although we maintain property, business interruption and casualty insurance that we believe is in accordance with customary industry practices, we cannot assure you that this insurance will be adequate to cover fully all potential hazards incidental to our business.

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**Environmental liabilities and compliance costs may have a significant adverse effect on our results of operations.**

The environmental laws of various jurisdictions impose actual and potential obligations on our Group to remediate contaminated sites. These obligations may relate to sites:

that we currently own or operate;

that we formerly owned or operated; or

where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. Sanofi accrues provisions for remediation when our management believes the need is probable and that it is reasonably possible to estimate the cost. See Item 4. Information on the Company B. Business Overview Health, Safety and Environment (HSE) for additional information regarding our environmental policies. In particular, our provisions for these obligations may be insufficient if the assumptions underlying these provisions prove incorrect or if we are held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have a material adverse effect on our results of operations and financial condition.

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi's subsidiaries have been named as potentially responsible parties or the equivalent under the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as Superfund), and similar statutes in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligation, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites of our predecessor companies, or our subsidiaries that we demerged, divested or may divest. We have disputes outstanding regarding certain sites no longer owned by the Group. An adverse outcome in such disputes might have a significant adverse effect on our operating results. See Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report.

Environmental regulations are evolving (*i.e.*, in Europe, REACH, CLP/GHS, SEVESO, IPPC, the Waste Framework Directive, the Emission Trading Scheme Directive, the Water Framework Directive and the Directive on Taxation of Energy Products and Electricity and several other regulations aiming at preventing global warming). Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Group and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance costs to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition. For more detailed information on environmental issues, see Item 4. Information on the Company B. Business Overview Health, Safety and Environment (HSE).

**Risks Related to Financial Markets<sup>1</sup>**

**Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.**

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Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the U.S. dollar, the British pound, the Japanese yen, and to currencies in emerging countries. In 2011, 29.8% of our net sales were realized in the United States. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of

<sup>1</sup> Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with respect to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements.



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adverse currency exchange rate fluctuations on our results of operations or financial condition. In addition, in the specific context of the sovereign debt crisis affecting certain European countries, the alleged or actual disruption in the use of the euro as currency in one or more European Monetary Union countries and the associated fluctuations in currency exchange rates could have a material effect on our financial condition and earnings, the magnitude and consequences of which are unpredictable. For more information concerning our exchange rate exposure, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

### **In the context of the worldwide financial crisis, our liquidity may be constrained.**

As of December 31, 2011, the Group's net debt amounted approximately to 10.9 billion, an amount which increased substantially with the acquisition of Genzyme in 2011. In addition to debt outstanding, the Group has contracted a number of credit lines and put into place commercial paper and medium term note programs with the aim of providing liquidity. See Item 11. Quantitative and Qualitative Disclosures about Market Risk. In the event of a market-wide liquidity crisis, the Group might be faced with reduced access to sources of financing, including under programs currently in place, or less favorable conditions.

### **Risks Relating to an Investment in our Shares or ADSs**

#### **Foreign exchange fluctuations may adversely affect the U.S. dollar value of our ADSs and dividends (if any).**

Holders of ADSs face exchange rate risk. Our ADSs trade in U.S. dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we do pay dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the U.S. dollar will affect the U.S. dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the U.S. dollar price of the ADSs on the New York Stock Exchange (NYSE), whether or not we pay dividends in addition to the amounts, if any, that a holder would receive upon our liquidation or upon the sale of assets, merger, tender offer or similar transactions denominated in euros or any foreign currency other than U.S. dollars.

#### **Persons holding ADSs rather than shares may have difficulty exercising certain rights as a shareholder.**

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we offer new shares and they have the right to subscribe for a portion of them, the depositary is allowed, at its own discretion, to sell for their benefit that right to subscribe for new shares instead of making it available to them. Also, to exercise their voting rights, as holders of ADSs, they must instruct the depositary how to vote their shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting.

#### **Our largest shareholders own a significant percentage of the share capital and voting rights of Sanofi.**

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As of December 31, 2011, L'Oréal and Total held approximately 8.82% and 3.22% of our issued share capital, respectively, accounting for approximately 15.69% and approximately 5.52%, respectively, of the voting rights (excluding treasury shares) of Sanofi. See Item 7. Major Shareholders and Related Party Transactions A. Major Shareholders. Affiliates of each of these shareholders are currently serving on our Board of Directors. To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, L'Oréal and Total will remain in a position to exert heightened influence in the election of the directors and officers of Sanofi and in other corporate actions that require shareholders' approval.

### **Sales of our shares may cause the market price of our shares or ADSs to decline.**

Neither L'Oréal nor Total is, to our knowledge, subject to any contractual restrictions on the sale of the shares each holds in our Company. Both of these shareholders have announced that they do not consider their stakes in our Company as strategic to them, and Total makes regular sales of its holdings on the financial market. Sales of large numbers of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs.

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**Risks Relating to our Contingent Value Rights (CVRs)**

**In addition to the risks relating to our shares, CVR holders are subject to additional risks.**

In connection with our acquisition of Genzyme, we issued CVRs under a CVR agreement entered into by and between us and American Stock Transfer & Trust Company, the trustee. A copy of the form of the CVR agreement is attached as exhibit 4.1 to our Registration Statement on Form F-4 (Registration No. 333-172638), as amended. Pursuant to the CVR agreement, each holder of a CVR is entitled to receive cash payments upon the achievement of certain milestones, based on U.S. regulatory approval of Lemtrada (alemtuzumab for treatment of multiple sclerosis), and on achievement of certain aggregate net sales thresholds. See Item 10. Additional Information C. Material Contracts The Contingent Value Rights Agreement.

CVR holders are subject to additional risks, including:

an active public market for the CVRs may not develop or the CVRs may trade at low volumes, both of which could have an adverse effect on the resale price, if any, of the CVRs;

because a public market for the CVRs has a limited history, the market price and trading volume of the CVRs may be volatile;

if the milestones specified in the CVR agreement are not achieved for any reason within the time periods specified therein, and if net sales do not exceed the thresholds set forth in the CVR agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire without value;

since the U.S. federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;

any payments in respect of the CVRs are subordinated to the right of payment of certain of our indebtedness;

we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise, and on November 17, 2011, Sanofi publicly disclosed that it has obtained the necessary corporate authorizations to acquire any or all of the outstanding CVRs (for more information see Item 5. Operating and Financial Review and Prospectus Liquidity. );

we may under certain circumstances purchase and cancel all outstanding CVRs; and

while we have agreed to use diligent efforts, until the CVR agreement is terminated, to achieve each of the Lemtrada -related CVR milestones set forth in the CVR agreement, we are not required to take all possible actions to achieve these goals, and the failure to achieve such goals would have an adverse effect on the value, if any, of the CVRs.

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### **Item 4. Information on the Company**

#### **Introduction**

We are a global pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. In 2011, our net sales amounted to 33,389 million. We are the fifth largest pharmaceutical group in the world and the third largest pharmaceutical group in Europe (source: IMS sales 2011). Sanofi is the parent of a consolidated group of companies. A list of the principal subsidiaries included in this consolidation is shown at Note F. to our consolidated financial statements included at Item 18 of this annual report.

Our business includes three main activities: Pharmaceuticals, Human Vaccines through Sanofi Pasteur and Animal Health products through Merial Limited (Merial).

In our Pharmaceuticals activity, which generated net sales of 27,890 million in 2011, our major product categories are:

*Diabetes:* our main products are Lantus<sup>®</sup>, a long acting analog of human insulin which is the leading brand in the insulin market; Apidra<sup>®</sup>, a rapid-acting analog of human insulin; Insuman<sup>®</sup>, a range of human insulin solutions and suspensions; Amaryl<sup>®</sup>, an oral once-daily sulfonylurea and BGStar<sup>®</sup> and iBGStar<sup>®</sup>, blood glucose meters first launched in Europe during the second quarter of 2011.

*Rare Diseases:* our principle products are enzyme replacement therapies: Cerezyme<sup>®</sup>, to treat Gaucher disease; Fabrazyme<sup>®</sup> to treat Fabry disease and Myozyme<sup>®</sup>/Lumizyme<sup>®</sup> to treat Pompe disease.

*Oncology:* our main products in the oncology market are Taxotere<sup>®</sup>, a taxane derivative representing a cornerstone therapy in several cancer types; Eloxatine<sup>®</sup>, a platinum agent, which is a key treatment for colorectal cancer; and Jevtana<sup>®</sup>, a new taxane derivative, indicated for patients with prostate cancer, launched in 2010 in the United States and in second quarter of 2011 in Europe.

*Other flagship products:* our thrombosis medicines include Plavix<sup>®</sup>, an anti-platelet agent indicated for a number of atherothrombotic conditions; and Lovenox<sup>®</sup>, a low molecular weight heparin indicated for prevention and treatment of deep vein thrombosis and for unstable angina and myocardial infarction. Our cardiovascular medicines include Multaq<sup>®</sup>, an anti-arrhythmic agent launched in 2009; and Aprovel<sup>®</sup>/CoAprovel<sup>®</sup>, major hypertension treatments. Our renal business includes Renegel<sup>®</sup>/Renvela<sup>®</sup> oral phosphate binders used in patients with chronic kidney disease on dialysis to treat high phosphorus levels. Our biosurgery business includes Synvisc<sup>®</sup> and Synvisc-One<sup>®</sup>, viscosupplements used to treat pain associated with osteoarthritis of certain joints.

The global pharmaceutical portfolio of Sanofi also comprises a wide range of other products in Consumer Health Care (CHC) and other prescription drugs including generics.

We are a world leader in the vaccines industry. Our net sales amounted to 3,469 million in 2011, with leading vaccines in five areas: pediatric combination vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines, and travel and endemics vaccines.

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Our Animal Health activity is carried out through Merial, one of the world's leading animal healthcare companies, dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners providing a comprehensive range of products to enhance the health, well-being and performance of a wide range of animals (production and companion animals). Our net sales amounted to 2,030 million in 2011.

In the description below, the following should be kept in mind:

A drug can be referred to either by its international non-proprietary name (INN) or by its brand name, which is normally exclusive to the company that markets it. In most cases, our brand names, which may vary from country to country, are protected by trademark registrations. In general, we have chosen in this annual report to refer to our products by the brand names we use in France, except for Allegra<sup>®</sup> (sold in France as Telfast<sup>®</sup>), Tritace<sup>®</sup> (sold in France as Triatec<sup>®</sup>), Amaryl<sup>®</sup> (sold in France as Amarel<sup>®</sup>), and Ambien<sup>®</sup> CR (an extended-release formulation of zolpidem tartrate, not sold in France).

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For our pharmaceutical activity, except where otherwise stated, all market share percentages and rankings are based on full-year 2011 sales figures from IMS Health MIDAS (retail and hospital).

For our vaccines activity, market shares and rankings are based on our own estimates. These estimates have been made from public domain information collated from various sources, including statistical data collected by industry associations and information published by competitors.

We present our consolidated net sales for our leading products sold directly and through alliances. As regards the products sold through our alliance with Bristol-Myers Squibb (BMS), we also present the aggregate worldwide sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup>, whether consolidated by Sanofi or by BMS. A definition of worldwide sales can be found in Item 5. Operating and Financial Review and Prospects Results of Operations .

### ***A. History and Development of the Company***

Sanofi was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. We operate under the commercial name Sanofi (formerly sanofi-aventis). Our registered office is located at 54, rue La Boétie, 75008 Paris, France, and our main telephone number is +33 1 53 77 40 00. Our principal U.S. subsidiary's office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981-5000.

We are present in approximately 100 countries on five continents with 113,719 employees at year end 2011. Our legacy companies, Sanofi-Synthélabo (formed by the 1999 merger of Sanofi and Synthélabo into the current holding company) and Aventis (formed by the combination of Rhône-Poulenc and Hoechst also in 1999), bring to the Group more than a century of experience in the pharmaceutical industry.

Sanofi was founded in 1973 by Elf Aquitaine, a French oil company, when it took control of the Labaz group, a pharmaceutical company. Its first significant venture into the U.S. market was the acquisition of the prescription pharmaceuticals business of Sterling Winthrop – an affiliate of Eastman Kodak – in 1994.

Synthélabo was founded in 1970 through the merger of two French pharmaceutical laboratories, Laboratoires Dausse (founded in 1834) and Laboratoires Robert & Carrière (founded in 1899). In 1973, the French cosmetics group L'Oréal acquired the majority of its share capital.

Hoechst traces its origins to the second half of the 19th century, to the time of the German industrial revolution and the emergence of the chemical industry. Traditionally active in pharmaceuticals, Hoechst strengthened its position in that industry by taking a controlling interest in Roussel-Uclaf in 1974 and the U.S. pharmaceutical company Marion Merrell in 1995.

Rhône-Poulenc was formed in 1928 from the merger of two French companies: a chemical company created by the Poulenc brothers and the Société Chimique des Usines du Rhône, which was founded in 1895. The company's activities in the first half of the 20th century focused on producing chemicals, textiles and pharmaceuticals. Rhône-Poulenc began to focus its activities on life sciences in the 1990s, which led to the successive purchases of Rorer, a U.S. pharmaceutical company acquired in two stages in 1990 and 1997, the remaining 49% of shares of Pasteur Mérieux Serums & Vaccins S.A. in 1994, and the U.K.-based pharmaceuticals company Fisons in 1995.

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Sanofi-Synthélabo took control of Aventis in August 2004 and changed its registered name to sanofi-aventis . On December 31, 2004, Aventis merged with and into sanofi-aventis, with sanofi-aventis as the surviving company.

In 1994, Pasteur Mérieux Serums & Vaccins, the Group's vaccines division, together with the vaccines division of Merck & Co., Inc. formed Sanofi Pasteur MSD, creating the only European firm entirely dedicated to vaccines.

Merial was founded in 1997 as a combination of the animal health activities of Rhône-Poulenc and Merck. Merial was a joint venture in which we and Merck each held 50%. On September 17, 2009, we acquired Merck's entire interest in Merial. Merial became Sanofi's dedicated animal health division following the joint statement issued by Merck and Sanofi in March 2011 announcing the end of their agreement to create a new animal health joint venture by combining their respective animal health segments. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report.

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Starting in 2009, Sanofi made a series of acquisitions to create or strengthen our regional CHC and generics platforms including:

The Prague-based branded generics group Zentiva was acquired by Sanofi through a tender offer completed on March 11, 2009;

On April 27, 2009, Sanofi acquired a 100% equity interest in Medley, the third largest pharmaceutical company in Brazil and a leading generics company in that country;

On February 9, 2010, Sanofi successfully completed its tender offer for all outstanding shares of common stock of Chattem, Inc., a leading U.S. consumer healthcare company. Immediately following the tender offer, Sanofi held approximately 97% of Chattem's outstanding shares, and acquired the remaining shares in a short form merger on March 10, 2010; and

On February 24, 2011, we acquired BMP Sunstone Corporation (a specialty pharmaceutical company with a proprietary portfolio of branded pharmaceutical and healthcare products in China) through a merger between BMP Sunstone and a wholly-owned subsidiary of ours.

On April 4, 2011, we acquired Genzyme Corporation, a leading biotechnology group headquartered in Cambridge, Massachusetts and specialized in the treatment of rare diseases, renal diseases, endocrinology, oncology and biosurgery. Immediately following the tender offer, Sanofi held over 90% of Genzyme's outstanding shares, and acquired the remaining shares in a short form merger on April 8, 2011. The agreement is described at Item 10. Additional Information C. Material Contracts .

As of the May 2011 General Meeting of Shareholders, the Group changed its name to Sanofi .

## ***B. Business Overview***

### **Strategy**

Sanofi is a diversified, global healthcare leader offering solutions across areas of core historical strength and multiple growth platforms. Like other pharmaceutical companies, we have been facing competition from generics for several of our major products, in an environment subject to cost containment pressures from both third party payers and healthcare authorities. Starting in 2009, we have responded to these major challenges by implementing a new strategy with the objective of repositioning Sanofi for more stable and sustainable revenue and earnings growth. During that time we have transformed the Company by decreasing our reliance on existing blockbuster medicines (medicines with over \$1 billion in global sales), optimizing our approach to Research & Development (R&D), increasing our diversification, and investing in 6 growth platforms (Emerging Markets<sup>(1)</sup>, Diabetes Solutions, Human Vaccines, Consumer Health Care, Animal Health, and Innovative Products). Additionally, we became a global leader in rare genetic diseases through our acquisition of Genzyme in 2011.

We regularly review our strategy and are continuing to execute on this strategy along three prongs:



**Increasing innovation in Research & Development (R&D)**

We have conducted a complete review of our research and development portfolio since 2009, in order to improve the allocation of our resources. This review has led to a rationalization of our portfolio, focusing on high-value projects and reallocating part of our resources from internal infrastructure to partnerships and collaborations. We also redefined our decision-making processes so that commercial potential and the scope for value creation are better integrated into our development choices. We also redesigned our R&D footprint including increasing our presence in the Boston, MA area with its concentration of universities and innovative biotechnology companies. R&D is now based on an organizational structure focused on patient needs and encouraging entrepreneurship. This network-based organization, open to external opportunities, enables our R&D portfolio to more effectively capitalize on innovation, from a wide range of sources.

- (1) We define Emerging Markets as the world excluding the United States, Canada, Western Europe (France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxemburg, Portugal, the Netherlands, Austria, Switzerland, Ireland, Finland, Norway, Iceland, Sweden and Denmark), Japan, Australia and New Zealand.

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In line with this policy, we signed new alliance and licensing agreements in 2011 designed to give us access to new technologies, and/or to broaden or strengthen our existing fields of research (including diabetes, oncology and vaccines). Finally, we have made progress on our objective of offering more products that add value for patients, with five New Molecular Entities (NMEs) submitted to regulatory agencies in 2011, and 18 potential new product launches possible before the end of 2015.

### **Adapting our structures to meet the opportunities and the challenges of the future**

Since 2009, we have adapted our operating model, from being focused on the best-selling prescription drugs in our traditional markets, to a broader set of products and services reflecting the diversity of our activities and our geographical reach. In particular, we tailored our strategy, structure and offering to each region's needs, so as to deliver the most appropriate solution to each patient. The result is a dramatic shift in business mix from Top 15 products to key growth platforms. In 2008, 61 % of our sales originated from our top 15 products while in 2011, 65 % of our sales originated from Genzyme and our growth platforms. Moreover, 30 % of our 2011 sales were in emerging markets where we have enhanced our offerings in high growth market segments such as Generics and Consumer Health Care by completing 17 transactions and investing a total of approximately \$3.7 billion in acquisitions over the last three years.

We also realigned our industrial capacity to reflect our expectation of changes in volumes and our analyses of growth opportunities. Combined with the streamlining of our R&D structures and keeping a tight control on SG&A expenses, this has helped enable us to successfully navigate through a period where multiple of our leading products faced the loss of patent exclusivity protection, despite an often tougher economic environment with new healthcare cost containment measures in many markets.

### **Exploring external growth opportunities**

Business development remains an integral and disciplined pillar of our overall strategy, targeting acquisitions and alliances that create and/or strengthen platforms for long-term growth and create value for our shareholders. Since January 2009, we have invested a total of approximately \$2.3 billion in external growth accounting for approximately 20% increase in 2011 consolidated sales. During 2011, we pursued this targeted policy actively, announcing 30 new transactions, including three acquisitions and 27 R&D alliances. We successfully completed our acquisition of Genzyme, a global leader in rare genetic diseases and an emerging leader in multiple sclerosis. We also strengthened our Emerging Markets growth platform with the acquisition of Universal Medicare, advancing our sustainable growth strategy in India and facilitating the creation of a Consumer Health Care platform in that country. Our U.S. vaccines operations were reinforced with the acquisition of Topaz Pharmaceuticals, which complements our pediatric offering.

In the years to come, we expect our sound financial position to provide us the potential to create value via external growth opportunities and to strengthen our diversification and growth platforms through new acquisitions and partnerships. We will remain financially disciplined with the aim of our business development activities to execute strategically important transactions and partnerships that secure a return on investment in excess of our cost of capital.

## **Pharmaceutical Products**

### **Main Pharmaceutical Products**

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Within our Pharmaceuticals business, we focus on the following categories: diabetes, rare diseases, oncology, and other flagship products in anti-thrombotics, cardiovascular, renal and biosurgery fields.

The sections that follow provide additional information on the indications and market position of our key products. Our intellectual property rights over our pharmaceutical products are material to our operations and are described at Patents, Intellectual Property and Other Rights below. As disclosed in Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Patents of this annual report, we are involved in significant litigation concerning the patent protection of a number of these products.

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The following table sets forth the net sales of our best-selling pharmaceutical products for the year ended December 31, 2011. These products are major contributors to public health.

<b>Therapeutic Area / Product Name</b>	<b>2011 Net Sales ( million)</b>	<b>Drug Category / Main Areas of Use</b>
<b>Diabetes</b>		
Lantus® (insulin glargine)	3,916	Long-acting analog of human insulin Type 1 and 2 diabetes mellitus
Apidra® (insulin glulisine)	190	Rapid-acting analog of human insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	436	Sulfonylurea Type 2 diabetes mellitus
Insuman® (insulin)	132	Human insulin (rapid and intermediate acting) Type 1 and 2 diabetes mellitus
<b>Rare Disease</b>		
Cerezyme® (imiglucerase for injection)	441 <sup>(1)</sup>	Enzyme replacement therapy Gaucher disease
Fabrazyme® (agalsidase beta)	109 <sup>(1)</sup>	Enzyme replacement therapy Fabry disease
Myozyme®/Lumizyme® (alglucidase alpha)	308 <sup>(1)</sup>	Enzyme replacement therapy Pompe disease
<b>Oncology</b>		
Taxotere® (docetaxel)	922	Cytotoxic agent Breast cancer  Non small cell lung cancer  Prostate cancer  Gastric cancer  Head and neck cancer
Eloxatine® (oxaliplatin)	1,071	Cytotoxic agent Colorectal cancer
Jevtana® (cabazitaxel)	188	Cytotoxic agent Prostate cancer
<b>Other Flagship products</b>		
Lovenox® (enoxaparin sodium)	2,111	Low molecular weight heparin Treatment and prevention of deep vein thrombosis  Treatment of acute coronary syndromes
Plavix® (clopidogrel bisulfate)	2,040	Platelet adenosine disphosphate receptor antagonist Atherothrombosis  Acute coronary syndrome with and without ST segment elevation
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	1,291	Angiotensin II receptor antagonist Hypertension
Multaq® (dronedarone)	261	Anti-arrhythmic drug Atrial Fibrillation

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<b>Therapeutic Area / Product Name</b>	<b>2011 Net Sales ( million)</b>	<b>Drug Category / Main Areas of Use</b>
Renagel® (sevelamer hydrochloride) / Renvala® (sevelamer carbonate)	415 <sup>(1)</sup>	Oral phosphate binders High phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis
Synvisc® / Synvisc-One® (hylan G-F 20)	256 <sup>(1)</sup>	Viscosupplements Pain associated with osteoarthritis of the knee
<b>Others</b>		
Stilnox® /Ambien®/Myslee® (zolpidem tartrate)	490	Hypnotic Sleep disorders
Allegra® (fexofenadine hydrochloride)	580 <sup>(2)</sup>	Anti-histamine Allergic rhinitis
Copaxone® (glatiramer acetate)	436	Urticaria Non-interferon immunomodulating agent
Tritace® (ramipril)	375	Multiple sclerosis Angiotensin Converting Enzyme inhibitor Hypertension
		Congestive heart failure
Depakine® (sodium valproate)	388	Nephropathy Anti-epileptic
Xatral® (alfuzosin hydrochloride)	200	Epilepsy Uroselective alpha1-blocker
Actonel® (risedronate sodium)	167	Benign prostatic hypertrophy Biphosphonate Osteoporosis
Nasacort® (triamcinolone acetonide)	106	Paget s disease Local corticosteroid Allergic rhinitis

(1) Since date of acquisition

(2) Excluding Allegra® OTC sales.

**Diabetes**

The prevalence of diabetes is expected to increase significantly over the next 20 years, reflecting multiple socio-economic factors including sedentary lifestyles, excess weight and obesity, unhealthy diet and an aging population. Our principal diabetes products are Lantus®, a long-acting analog of human insulin; Apidra®, a rapid-acting analog of human insulin; Insuman®, a human insulin; and Amaryl®, a sulfonylurea. In 2011, in some European markets, we launched the BGStar® solution range of blood glucose meters for patients with diabetes, whether they are treated with insulin or not.

**Lantus®**

Lantus® (insulin glargine) is a long-acting analog of human insulin, offering improved pharmacokinetic and pharmacodynamic profiles compared to other basal insulins. Lantus® is indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus who require basal insulin for the control of hyperglycemia, and for adult and pediatric patients aged six years and above with type 1 diabetes mellitus.



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Lantus® is a well-established treatment with over 38 million patient-years exposure since 2000. The clinical trial experience with Lantus® covers over 100,000 patients.

Lantus® can be administered subcutaneously using syringes or specific pens including:

Lantus® SoloSTAR® is a pre-filled disposable pen available in over 50 countries worldwide. It is the only disposable pen that combines a low injection force, up to 80 units per injection, and ease-of-use; and

ClikSTAR® is a reusable insulin pen first approved in 2009 in the European Union and Canada. It is now available in more than 35 countries worldwide.

In September 2009, following four highly publicized but methodologically limited registry analyses, some of which created concern over a potential link between the use of Lantus® and an increased risk of cancer, we announced an action plan to provide methodologically robust research that will contribute to the scientific resolution of the debate over insulin safety, including insulin analogs and Lantus®. The research program encompasses both preclinical and clinical programs involving human insulin and insulin analogues, including insulin glargine; it is designed to generate more information on whether there is any association between cancer and insulin use, and to assess whether there is any difference in risk between different types of insulins. The plan is structured to yield short-term and longer-term results. Three epidemiological studies (two retrospective cohort studies and one case-control study) have been launched:

the Northern European Study will compare the risk of cancer in adults prescribed insulin glargine versus those prescribed human insulin, and other types of insulin, and in all users of insulin combined. The results of the Northern European Database Study of Insulin and Cancer Risk are under review by health authorities and will be presented to scientific conferences in 2012. These results confirm Sanofi's confidence in the safety of Lantus®;

the U.S. Study will compare the risk of breast, prostate and colon cancer (each considered separately) in glargine users versus human NPH insulin users. Study completion is for the end of the first half of 2012; and

the International Study of Insulin and Cancer, being carried out in the United Kingdom, France and Canada, will assess the association of breast cancer with the use of insulins. The study results are expected by end 2012.

The ADA/ACS (American Diabetes Association / American Cancer Society) Consensus Report published on June 16, 2010 reasserted the inconclusiveness of any link between insulin and cancer.

In January 2011, the FDA updated its ongoing safety review of Lantus®. In addition to the analysis of the four registry analyses published in 2009, the FDA also reviewed results from a five-year diabetic retinopathy clinical trial in patients with type 2 Diabetes. Based on these data, the FDA has not concluded at this time that Lantus® increases the risk of cancer. FDA review remains ongoing.

In December 2011, results of new meta-analysis were presented at the World Diabetes Congress. This new meta-analysis of all published studies observational studies derived from databases as well as randomized controlled clinical trials and one case-control study has demonstrated no increased risk in people using Lantus® when compared to the users of human insulin.

The ADA and European Association for the Study of Diabetes (EASD) have maintained their 2008 treatment recommendations for type 2 diabetes. These guidelines further established basal insulins such as Lantus<sup>®</sup>, or a sulfonylurea such as Amaryl<sup>®</sup>, as two preferred second-line treatment options for people with diabetes who are unable to achieve glycemic control targets with lifestyle intervention and metformin alone. These treatment recommendations reinforce the timely use of basal insulin as a core therapy for type 2 diabetes.

Lantus<sup>®</sup> is the world number-one selling insulin brand in terms of both sales and units (source: IMS, 2011 sales) and is available in over 70 countries worldwide. The three leading countries for sales of Lantus<sup>®</sup> in 2011 were the United States, France and Japan.



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### **Apidra®**

Apidra® (insulin glulisine) is a rapid-acting analog of human insulin. Apidra® is indicated for the treatment of adults with type 1 diabetes, or in type 2 diabetes for supplementary glycemic control. Apidra® has a more rapid onset and shorter duration of action than fast-acting human insulin and can be associated with long-acting insulins such as Lantus® for supplementary glycemic control at mealtime.

In addition, Apidra® is equally effective in adult diabetics ranging from lean to obese and offers patients greater flexibility of administration, either before or just after mealtime.

Apidra® can be administered subcutaneously using syringes or specific pens including the Apidra® SoloSTAR® disposable pen and the ClikSTAR® reusable pen.

Apidra® is available in over 60 countries worldwide.

Due to a technical incident on a manufacturing line, Apidra® faced a temporary shortage of Apidra® 3mL cartridges (including Apidra® SoloSTAR®) which impacted supplies in some markets. The production of Apidra® 3mL cartridges is expected to return to full capacity in the first half of 2012. Apidra® vials were not impacted.

### **Insuman®**

Insuman® (human insulin) is a range of insulin solutions and suspensions for injection and is indicated for diabetes patients where treatment with insulin is required. Human insulin is produced by recombinant DNA technology in *Escherichia coli strains*.

Insuman® is supplied in vials, cartridges, pre-filled disposable pens (OptiSet® and SoloStar®) or reusable pens (ClickSTAR®) containing the active substance human insulin. The Insuman® range is comprised of rapid-acting insulin solutions (Insuman® Rapid and Insuman® Infusat) that contain soluble insulin, an intermediate-acting insulin suspension (Insuman® Basal) that contains isophane insulin, and combinations of fast- and intermediate-acting insulins in various proportions (Insuman® Comb). Insuman® is mostly sold in Germany.

### **Amaryl®/Amarel®/Solosa®**

Amaryl® (glimepiride) is a latest-generation, orally administered once-daily sulfonylurea (a glucose-lowering agent) indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Amaryl® reduces the body's blood sugar level in two ways: by helping the body to produce more insulin both at mealtime and between meals, and by decreasing insulin resistance.

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The combination of metformin (which reduces hepatic glucose production and decreases insulin resistance) with a sulfonylurea such as Amaryl<sup>®</sup> is effective in combating the two causes of type 2 diabetes. It is one of the most prescribed combinations of diabetes drugs worldwide. Amaryl M<sup>®</sup>, a fixed-dose combination of Amaryl<sup>®</sup> plus metformin in a single presentation, was launched in 2007.

Our leading market for Amaryl<sup>®</sup> is Japan, where it is the best-selling oral anti-diabetes product by volume (source: IMS 2011 sales). A number of generics have received marketing authorization and have been launched in Europe and the United States. Generic became available in Japan in November 2010 but the impact on Amaryl<sup>®</sup> sales compared to the impact of generic sales generally observed in the U.S. or the EU has been more moderate.

### **BGStar<sup>®</sup> / iBGStar**

Sanofi and its partner AgaMatrix are co-developing innovative solutions in diabetes care with the aim of simplifying the diabetes management experience for patients and healthcare providers. The blood glucose monitoring solutions will be exclusive to Sanofi and are designed to be synergistic with our Diabetes portfolio, with a positive effect on sales of Lantus<sup>®</sup> and other products expected.

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BGStar® and iBGStar are blood glucose meters that feature Dynamic Electrochemistry®, an innovative technology that extracts a spectrum of information from blood that is inaccessible to traditional electrochemical methods and compensates for many interfering factors that often distort blood glucose results.

These monitoring devices are an important step towards our vision of becoming the global leader in diabetes care by integrating innovative monitoring technology, therapeutic innovations, personalized services and support solutions. During 2011, the BGStar® and iBGStar were made commercially available in Germany, France, Switzerland, Spain, the Netherlands and Italy.

In December 2011, the FDA approved the iBGStar the first blood glucose meter that connects to the iPhone® allowing patients to view and analyze accurate, reliable information in real time .

### **The main compounds currently in Phase II or III clinical development in the Diabetes/Other Metabolic Disorders field are:**

**Lixisenatide** (AVE0010 GLP-1: Glucagon-like peptide-1 agonist, type 2 diabetes mellitus; Phase IIIb; lixisenatide is in-licensed from Zealand Pharma A/S). The GETGOAL Phase III studies were finalized and demonstrated that lixisenatide was effective in lowering blood sugar and decreasing body weight with good safety and tolerability. These results were presented at international conferences (e.g. ADA, EASD, IDF). Lixisenatide was submitted in the fourth quarter of 2011 to EMA, Switzerland, Mexico, Brazil, Canada, Ukraine, South Africa and Australia. Additional Phase IIIb studies have been initiated.

Phase I studies on combination of lixisenatide and Lantus® have been successfully finalized. A proof-of-concept study to compare insulin glargine/ lixisenatide fixed ratio combination versus insulin glargine on glycemic control over 24 weeks has begun.

Preliminary Phase II results of **SAR236553**, co-developed with Regeneron (REGN727: anti-PCSK9 mAb), have been obtained. Treatment with SAR236553 leads to mean relative LDL-Cholesterol reduction of greater than 65% after 8-12 weeks of treatment in patients with high LDL-C at baseline.

The partnership with Metabolex on the GPR119 receptor agonist **SAR260093** has been terminated.

## ***Oncology***

Sanofi is present in the oncology field, primarily in chemotherapy, with three major products: Taxotere®, Eloxatine®, and Jevtana®, which was launched commercially in the United States in 2010 and in the second quarter of 2011 in Europe.

### **Taxotere®**

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Taxotere® (docetaxel), a taxoid class derivative, inhibits cancer cell division by essentially freezing the cell's internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell cycle. Taxotere® promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing and resulting in death in many cancer cells.

Taxotere® is available in more than 100 countries as an injectable solution. The single vial formulation (one vial IV route 20-80mg) was launched in the U.S. and in the European Union in 2010. It has gained approval for use in eleven indications in five different tumor types (breast, prostate, gastric, lung, and head and neck). Taxotere® is indicated for early stage and metastatic breast cancer, first-line and second-line metastatic Non-Small Cell Lung Cancer (NSCLC), androgen-independent (hormone-refractory) metastatic prostate cancer, advanced gastric adenocarcinoma (including adenocarcinoma of the gastroesophageal junction), and the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

The top four countries contributing to sales of Taxotere® in 2011 were the United States, Japan, France, and China. Generics of docetaxel were launched at the end of 2010 in Europe and in April 2011 in the U.S. Exclusivity for Taxotere® in Japan will be maintained through November 2013 (see Patents, Intellectual Property and Other Rights below).

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### **Eloxatin®**

Eloxatin® (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatin® combined with infusional (delivered through the bloodstream) administration of two other chemotherapy drugs, 5-fluorouracil/leucovorin (the FOLFOX regimen), is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary (original) tumors surgically removed. This approval was based on evidence of an improvement in disease-free survival after four years.

Eloxatin® is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide.

Following the end of the Eloxatin® European regulatory data exclusivity in April 2006, a number of oxaliplatin generics have been launched throughout Europe. With regard to the U.S. market, a number of oxaliplatin generics received final marketing authorization from the FDA and were marketed until June 30, 2010, when their manufacturers were ordered by the U.S. District Court for the District of New Jersey to cease selling their unauthorized Eloxatin® generic in the United States. Eloxatin U.S. market exclusivity is expected to be maintained through August 9, 2012. See Item 8. Financial Information A. Consolidated Financial Statements and other Financial Information Patents .

### **Jevtana®**

Jevtana® (cabazitaxel) is a new taxane derivative approved in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. Jevtana® was the result of a 14-year research and development program to address the significant unmet medical need after taxane-based treatment progression.

The results of the TROPIC Phase III study demonstrated that cabazitaxel plus prednisone/prednisolone significantly improved overall survival versus the standard regimen of mitoxantrone plus prednisone/prednisolone in patients with metastatic hormone-refractory prostate cancer whose disease progressed following treatment with docetaxel-based chemotherapy. A combination of cabazitaxel and prednisone/prednisolone significantly reduced the risk of death by 28% with an improvement in median overall survival of 15.1 months vs. 12.7 months in the mitoxantrone combination arm.

Jevtana® was launched in the United States in July 2010. Jevtana® therapy is now covered by CMS (Committee for Medicare and Medicaid Services), and by most of the private insurance companies that pay for oncology care. In addition, the safety profile seen in clinical practice has been consistent with that seen in the pivotal TROPIC study.

In March 2011, Jevtana® received marketing authorization from the European Commission and was launched during the second quarter of 2011 in Germany and France. Jevtana® is now approved in 53 countries.

Sanofi has initiated a broad development program with Jevtana®. The clinical program is projected to evaluate Jevtana® in first- and second-line treatment of prostate cancer patients, second-line treatment of small-cell lung cancer patients, and patients with advanced gastric cancer.

The top four countries contributing to sales of Jevtana® in 2011 were the United States, Germany, Brazil and France.

**The main compounds currently in Phase II or III clinical development in the Oncology field are:**

**Zaltrap**®, also known as aflibercept, is an investigational angiogenesis inhibitor with a unique mechanism of action. This fusion protein binds all forms of Vascular Endothelial Growth Factor-A (VEGF-A), as well as VEGF-B and placental growth factor (PlGF), additional angiogenic growth factors that appear to play a role in tumor angiogenesis and inflammation. Zaltrap has been shown to bind VEGF-A, VEGF-B, and PlGF with higher affinity than their native receptors. Sanofi Oncology and Regeneron are collaborating on a broad oncology development program for Zaltrap. The Phase III clinical program was designed to evaluate Zaltrap in combination with common chemotherapy regimens

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in the treatment of patients with advanced cancers, including cancers where bevacizumab has not demonstrated efficacy. Patients who had previously received bevacizumab were also included in the clinical trials for certain second-line treatment settings. In June 2011, Sanofi announced the positive results from VELOUR, a multinational, randomized, double-blind trial comparing the FOLFIRI (irinotecan-5-fluorouracil-leucovorin) chemotherapy regimen in combination with either Zaltrap or placebo in the treatment of patients with mCRC. The study randomized 1,226 patients with mCRC who previously had been treated with an oxaliplatin-based regimen. About one-third of the participants received bevacizumab as part of their first-line therapy. The primary endpoint was an improvement in overall survival. Secondary endpoints included progression-free survival, response to treatment and safety. Results were first presented at the ESMO World Congress on Gastrointestinal Cancer on June 25, 2011. The abstract (#0-0024) was published in the June 2011 supplement to Annals of Oncology. The current development program also explores Zaltrap for the treatment of metastatic prostate cancer with VENICE: First-line treatment for androgen-independent (hormone-refractory) metastatic prostate cancer in combination with docetaxel and prednisone (Phase III). Final results are anticipated in 2012. The aflibercept dossier was accepted for review by the EMA at the end of 2011. A NDA was filed in February 2012.

**Semuloparin** is a novel ultra-low-molecular-weight heparin (ULMWH) characterized by a high anti-Xa and a residual anti-IIa activity. Semuloparin's binding feature is directly responsible for the prolonged half-life (16-20 hours). In the Phase III placebo-controlled SAVE-ONCO trial, whose results were presented at ASCO 2011, Semuloparin has been investigated for its use in the prophylaxis of venous thromboembolism (VTE) in 3,212 cancer patients receiving chemotherapy for locally advanced or metastatic solid tumors (lung, pancreas, stomach, colon/rectum, bladder or ovary). Overall, Semuloparin 20mg once daily administered subcutaneously over a mean treatment duration of 3.2 months, significantly reduced VTE or VTE related death by 64% and PE by 59% vs placebo. The treatment effect was consistent across the components of primary endpoint, DVT and PE, cancer type, stage and various levels of VTE risk. The incidence of major bleeding was similar in the two groups: 1.2% and 1.1% in the Semuloparin and placebo groups, respectively. Further study analyses by sub-groups have been presented in oral presentations at ESMO and ASH 2011. A new drug application (NDA) has been accepted for review by the FDA and the EMA end of October 2011. Semuloparin is expected to be the first anti-coagulant approved for the indication of VTE prophylaxis in cancer patients receiving chemotherapy.

**BSI-201** (iniparib SAR240550) is an agent with novel mechanism of activity that is currently being studied in advanced squamous non-small cell lung cancer (Phase III) as well as ovarian and breast cancers (Phase II). While the initial dosing regimen was based on the putative PARP inhibitory activity, current efforts are aimed at elucidating the mechanism of action and exploring the maximal tolerated dose both as a single agent and in combination with chemotherapy.

**Ombrabulin** (AVE8062; combretastatin derivative, a new anti-vascular agent in-licensed from Ajinomoto; sarcoma; Phase III). Single agent and combination studies with platinum and taxanes alone or in combination have been conducted with ombrabulin. A Phase III study in soft tissue sarcoma in combination with cisplatin was initiated in 2008 and will terminate enrollment in 2012. Ombrabulin is also investigated in a Phase II trial in Non-Small-Cell Lung Cancer in combination with taxanes and platinum salts, which is over 90% enrolled and will report results in 2012, as well as in an ongoing Phase II trial in ovarian cancer.

**SAR302503** (TG101348) was purchased from Targegen in 2009 and is being developed exclusively by Sanofi. SAR302503 is a selective oral, small molecule inhibitor of the JAK2 kinase. JAK2 and the JAK/stat pathway have been identified as key regulators of growth and differentiation of normal hematopoietic cells, and are commonly dysregulated in multiple myeloproliferative disorders, including myelofibrosis (MF), polycythemia vera (PV), and essential thrombocytosis (ET). SAR302503 is now in Phase III, being investigated in the JAKARTA trial, a global Phase III trial of SAR302503 in primary and secondary myelofibrosis. The unique ability of SAR302503 to decrease allele burden will be further explored in the JAKARTA trial. In addition, a Phase II study in MF has recently completed accrual. Also ongoing is a Phase II trial in hydroxyurea-resistant PV and ET.

**SAR245408** (XL147) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This phosphoinositide-3-kinase (PI3K) inhibitor is under evaluation in a Phase II study of monotherapy for

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the treatment of advanced or recurrent endometrial cancer. Combinations with paclitaxel/carboplatin, letrozole and trastuzumab are also being evaluated. Phase I trials of novel combinations with MSC1936369B (under a collaboration with Merck Serono, a division of Merck KGaA, Darmstadt, Germany) and MM121 (see below) have been initiated.

**SAR245409** (XL765) was also in-licensed from Exelixis, Inc. and is being developed under an alliance by Sanofi. This oral agent is an inhibitor of phosphoinositide-3-kinase (PI3K) and also acts against the mammalian target of rapamycin (mTOR). A Phase I/II study in combination with letrozole for the treatment of metastatic hormone-receptor-positive breast cancer is ongoing and a Phase II trial in mantle cell lymphoma, follicular lymphoma and chronic lymphocytic leukemia has been initiated. Combinations with temozolomide, bendamustine and rituximab are also being evaluated.

**SAR256212 (MM-121)**. Under an exclusive global collaboration and licensing agreement, Merrimack and Sanofi are co-developing SAR256212, a fully human monoclonal antibody targeting ErbB3. ErbB3 has been identified as a key node in tumor growth and survival. SAR256212 blocks Heregulin binding to ErbB3, and formation of pErbB3 and pAKT. Given SAR256212's mode of action, it has the potential to be used in a wide number of tumors and settings. SAR256212 is in Phase II stage of development (Breast, Lung and Ovarian cancers), while a number of combinations with chemotherapy and targeted agents are being explored in the Phase I program. A companion diagnostic tool is being developed in parallel with the clinical program.

**SAR3419** (Antibody Drug Conjugate (ADC) maytansin-loaded anti-CD19 mAb; B-cell malignancies: B-Non Hodgkin's Lymphomas (NHL), B-Acute Lymphoblastic Leukemias (ALL). License from IMMUNOGEN inc.). The clinical development program is entering Phase II stage in Diffuse Large B Cell Lymphoma (DLBCL, aggressive lymphoma type) with the aim of confirming the clinical benefit observed in patients during Phase I trials. Ongoing/Planned trials in unmet medical need subsets of patients are: one Phase II study as single agent and one study in combination with Rituximab (rituxan, anti CD20 mAb) in Relapsed/Refractory (R/R) DLBCL patients. A biomarker exploratory sub-study is associated to the clinical NHL program in order to evaluate drivers for anti tumor response. In parallel, preclinical experiments to identify potential synergistic combinations (hypothesis driven combinations and unbiased in vitro screens) are being performed. A second indication is developed in a setting of large medical need, with the start of one exploratory Phase II study in adult patients with R/R ALL.

**Clorafabine** (Clolar® / Evoltra®) (Genzyme) (Purine-nucleosid analog). A Phase III program is on going in the treatment of acute myeloid leukemia.

In 2011, we conducted several additional collaborations with other companies, universities and institutes to investigate novel oncology agents (see Pharmaceutical Research & Development Portfolio below).

***Collaborations with Regeneron***

We and Regeneron globally collaborate on the development and commercialization of Zaltrap®. Under the terms of our September 2003 collaboration agreement, as amended, we and Regeneron will share co-promotion rights and profits on sales, if any, of Zaltrap® outside of Japan for disease indications included in our collaboration. In Japan, Sanofi will develop and commercialize Zaltrap®, with Regeneron entitled to a royalty payment. Under the terms of the agreement, Sanofi is responsible for funding 100% of the development costs of Zaltrap®. Once Zaltrap® starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by Sanofi) in accordance with a formula based on Regeneron's share of the profits. Sanofi may also be responsible for making milestone payments upon receipt of specified marketing approvals for Zaltrap® in the United States or the European Union and in Japan.

In November 2007, Sanofi signed additional agreements with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies. These agreements were broadened, and their term extended, on November 10, 2009. Under the terms of the discovery agreement, Sanofi committed to fund the costs of Regeneron's antibody research program until 2017. Sanofi has an option to license for further development



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those antibodies discovered by Regeneron which advance to IND. Upon exercise of the option, Sanofi is primarily responsible for funding the development and co-developing the antibody with Regeneron. Sanofi and Regeneron would also share co-promotion rights and profits on sales. Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) 50% of the development costs borne by Sanofi for all antibodies licensed by Sanofi. Sanofi may also be responsible for making milestone payments based upon aggregate sales of antibodies under the collaboration.

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### ***Rare Diseases***

The acquisition of Genzyme in April 2011 brought to the Group specific expertise in rare diseases, a sector where there are still many unmet needs, and expanded Sanofi's presence in the biotechnology sector.

Our Rare Disease business is focused on products for the treatment of rare genetic diseases and other chronic debilitating diseases, including lysosomal storage disorders, or LSDs, a group of metabolic disorders caused by enzyme deficiencies. Our principle rare disease products are enzyme replacement therapies: Cerezyme® (imiglucerase for injection) to treat Gaucher disease; Fabrazyme® (agalsidase beta) to treat Fabry disease and Myozyme® / Lumizyme® (alglucosidase alfa) to treat Pompe disease.

### **Cerezyme®**

Cerezyme® (imiglucerase for injection) is an enzyme replacement therapy that is used to treat Gaucher disease, an inherited, potentially life-threatening LSD. It is estimated that there are approximately 10,000 Gaucher patients worldwide.

Cerezyme® is the only therapy with a 17-year history of reducing, relieving and reversing many of the symptoms and risks of Type 1 Gaucher disease. Cerezyme® is administered by intravenous infusion over 1-2 hours.

In June 2009, Genzyme interrupted production of Cerezyme® and Fabrazyme® at its Allston facility after identifying a virus in a bioreactor used for Cerezyme® production. Genzyme resumed Cerezyme® shipments in the fourth quarter of 2009. This interruption was followed by a second one in March 2010 resulting from a municipal electrical power failure that compounded issues with the facility's water system.

Genzyme communicated at the end of 2011 that, given current productivity and progress in the manufacturing recovery, we expect an improving supply outlook as the year progresses. We have begun communicating with the U.S. Gaucher community to inform them that, beginning in February 2012, current patients in the U.S. can be returned to normal dosing. Genzyme will also begin the process of returning additional regions globally back to normal supply. This process will begin in the second quarter of 2012 and continue gradually through the remainder of the year, to ensure that a ramp-up can be sustained. Regions outside of the U.S. will be maintained at their current allocation of Cerezyme®, as Genzyme assesses the timing of the return of additional regions to full supply. No regional allocation will be decreased to accommodate the U.S. ramp-up. We continue to make Cerezyme® available to patients as it is produced. However, since we have minimal inventory, any change to our manufacturing plans can have an immediate impact on our ability to provide product.

The principal markets for Cerezyme® are the United States, Latin America and Europe.

### **Fabrazyme®**

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Fabrazyme® (agalsidase beta) is an enzyme replacement therapy that is used to treat Fabry disease, an inherited, progressive and potentially life-threatening LSD. Fabry disease is estimated to affect between 5,000 and 10,000 people worldwide. Fabrazyme® is administered by intravenous infusion.

Fabrazyme® is available in over 30 countries, including the United States and Europe, and has been used in hundreds of patients.

Due to the June 2009 production interruption and low manufacturing productivity upon re-start of production, Fabrazyme® shipments decreased in the fourth quarter of 2009 and Genzyme began shipping Fabrazyme® at a rate equal to 30% of estimated product demand. Throughout 2011, Genzyme has maintained consistent supply of Fabrazyme® to current patients at a reduced dose. To return to normal supply levels of Fabrazyme® for existing and new patients, it will be necessary to utilize the additional capacity from Genzyme's new manufacturing facility in Framingham, Massachusetts, that was approved in January 2012 by the FDA and the EMA. Genzyme will begin the process of moving the most severely affected patients in Europe to full dose of Fabrazyme® during the first quarter of 2012. Beginning in March 2012 in the U.S., all patients currently on therapy are expected to be able to return to full dosing (1mg/kg). In addition, Genzyme will begin to transition

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new patients in the U.S. onto Fabrazyme® at full dosing (1mg/kg) levels. Beginning of March, Genzyme started shipping Fabrazyme® from Framingham. Globally, the return to normal supply levels of Fabrazyme® is expected to begin in the second quarter of 2012 and continue throughout the year as planned, as Genzyme works to obtain all global regulatory approvals throughout the year and to build inventory.

The principal markets for Fabrazyme® are the United States and Europe.

### **Myozyme® / Lumizyme®**

Myozyme® / Lumizyme® (alglucosidase alfa) are enzyme replacement therapies used to treat Pompe disease, an inherited, progressive and often fatal LSD. We estimate that there are approximately 10,000 Pompe patients worldwide.

Myozyme® has been marketed since 2006 in the United States and the EU and is currently available in 48 markets worldwide. Lumizyme® is the first treatment approved in the United States specifically to treat patients with late-onset Pompe disease: Lumizyme® has been marketed since June 2010. Myozyme® and Lumizyme® are administered by intravenous infusion. Lumizyme® is used to treat Pompe disease in patients over 8 years of age without evidence of cardiac hypertrophy.

Both products are a recombinant form of the same human enzyme but are manufactured using different sized bioreactors.

### **The main compounds currently in Phase II or III clinical development in the Rare Diseases field are:**

**Eliglustat tartrate** Substrate reduction therapy targeted for the treatment of Gaucher disease type 1. This product candidate is administered orally in capsule form and has the potential to transform the treatment experience of patients by providing a treatment alternative to bi-weekly infusions. The first three years of data from the Phase II trial of eliglustat tartrate showed clinically significant improvements in hematological, visceral and bone disease parameters in the range expected for enzyme replacement therapy. During 2011, the two pivotal Phase III registration studies completed enrollment and the third Phase III study closed screening. Its recruitment should be completed in 2012.

### ***Other Flagship Products***

#### **Lovenox®/Clexane®**

Lovenox® (enoxaparin sodium) is available in over 100 countries, it has been used to treat over 350 million patients since its launch.

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Lovenox<sup>®</sup> has the broadest range of indications amongst low molecular weight heparins (LMWH). A comprehensive clinical development plan has demonstrated the efficacy and safety of Lovenox<sup>®</sup> in the prevention and treatment of venous thrombo-embolism (VTE) and in the management of the full spectrum of acute coronary syndromes (ACS).

In VTE management, Lovenox<sup>®</sup> is continuing to grow as a treatment for the prevention of VTE, mainly in acutely ill patients not undergoing surgery.

In 2008, new oral anticoagulants were launched for the prevention of VTE in orthopedic surgery and were approved in 2011 for stroke prevention in patients with atrial fibrillation, with the objective to replace vitamin K antagonists (e.g. warfarin). However, the impact has been limited on Lovenox<sup>®</sup> usage as prevention of VTE in orthopedic surgery is a small segment of Lovenox<sup>®</sup> usage and as stroke prevention in atrial fibrillation is not a Lovenox<sup>®</sup> approved indication.

In VTE prophylaxis in acutely ill medical patients, a major market segment for Lovenox<sup>®</sup>, two large clinical trials have compared new oral anti-coagulants to Lovenox<sup>®</sup>: extended prophylaxis using new oral anti-coagulants has not shown added benefit compared to short term prophylaxis using Lovenox<sup>®</sup>.

Competing generics of enoxaparin were launched respectively in July 2010 and in February 2012 in the U.S. An authorized generic is available in the U.S.. See Item 5. Operating and Financial Review and Prospects Impacts from generic competition .

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In 2011, Lovenox<sup>®</sup> was the leading anti-thrombotic in Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2011 sales).

### **Plavix<sup>®</sup>/Iscover<sup>®</sup>**

Plavix<sup>®</sup> (clopidogrel bisulfate), a platelet adenosine diphosphate (ADP) receptor antagonist with a rapid onset of action that selectively inhibits platelet aggregation induced by ADP, is indicated for long-term prevention of atherothrombotic events in patients with a history of recent myocardial infarction, recent ischemic stroke or established peripheral arterial disease. Plavix<sup>®</sup> is indicated for the secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). This indication is supported by the results of the landmark CAPRIE trial, including almost 20,000 patients. CAPRIE demonstrated the superior efficacy of Plavix<sup>®</sup> over acetylsalicylic acid (ASA, the active ingredient of Aspirin<sup>®</sup>), with a comparable safety profile.

Following the significant results of several clinical trials, involving a total of almost 62,000 patients, Plavix<sup>®</sup> is now also indicated for the treatment of acute coronary syndrome (ACS) with and without ST segment elevation in combination with ASA.

Plavix<sup>®</sup> is also available in a 300 mg tablet that reinforces early use by simplifying its approved loading dose administration in patients with ACS.

In January 2011, on the basis of the ACTIVE A study results (7,554 patients), the EMA granted marketing authorization for Plavix<sup>®</sup> in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke, in patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA), and have a low bleeding risk.

A Phase III mortality and shunt-related morbidity study in infants palliated with a systemic to pulmonary artery shunt was completed in 2010. Even though results did not support an indication in such infants, the FDA granted Sanofi an additional six month period of exclusivity to market Plavix<sup>®</sup> (clopidogrel bisulfate). Exclusivity for Plavix<sup>®</sup> in the U.S. is now scheduled to expire on May 17, 2012.

To further characterize patient responsiveness to Plavix<sup>®</sup> and provide the best guidance to healthcare professionals, a clinical program designed in close collaboration with the FDA has been completed by Sanofi and Bristol-Myers Squibb (BMS). Based on this program the label was updated worldwide in 2010, including new results on the pharmacological interaction of omeprazole with Plavix<sup>®</sup> and recent pharmaco-genomics data which have shown genomic variability of the response to Plavix<sup>®</sup> treatment (diminished effectiveness in poor metabolizers). This has been highlighted in the U.S. label with a boxed warning.

The extensive clinical development program for Plavix<sup>®</sup>, including all completed, ongoing and planned studies, is among the largest of its kind, involving more than 130,000 patients overall. Plavix<sup>®</sup> indications are incorporated into major scientific guidelines in North America, Europe and Japan. Over 115 million patients are estimated to have been treated with Plavix<sup>®</sup> since its launch in 1998, providing significant evidence of real-life efficacy and safety experience with this product.

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CoPlavix® / DuoPlavin®, a fixed dose combination of clopidogrel bisulfate and acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and ASA. The combination has already been launched in several countries (including Australia, Germany, the Netherlands, Ireland, Spain, and Mexico).

The marketing of Plavix® / CoPlavix® / DuoPlavin® is organized through our alliance with BMS (see Alliance with BMS below). Sales of Plavix® in Japan are consolidated by Sanofi and are outside the scope of our alliance with BMS.

Plavix® is the leading anti-platelet in the U.S., Chinese and Japanese markets (source: IMS 2011 sales). In Europe, a number of generics have received marketing authorization and have been launched. Plavix® market

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share <sup>(1)</sup> by value was 29.1% in Western Europe and 27.2% in Germany (source: IMS 2011 sales). In Canada, generics were launched in December 2011. Plavix<sup>®</sup> U.S. market exclusivity is expected to be maintained through May 2012.

### **Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>**

Aprovel<sup>®</sup> (irbesartan) is an anti-hypertensive belonging to the class of angiotensin II receptor antagonists. These highly effective and well tolerated antagonists act by blocking the effect of angiotensin II, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>, we also market CoAprovel<sup>®</sup>/Avalide<sup>®</sup>/Karvezide<sup>®</sup>, a fixed dose combination of irbesartan and hydrochlorothiazide (HCTZ), a diuretic that increases the excretion of water and sodium by the kidneys and provides an additional blood pressure lowering effect. These products achieve control of blood pressure in over 80% of patients, with a very good safety profile.

Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> tablets are available in a wide range of dosages to fit the needs of patients with different levels of hypertension severity.

Aprovel<sup>®</sup> is indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. CoAprovel<sup>®</sup> is indicated in patients whose blood pressure is not adequately controlled with a monotherapy, but also as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals (in the United States only).

Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> are marketed in more than 80 countries. The marketing of Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> is organized through an alliance with BMS (see Alliance with BMS below). In Japan, the product is licensed/sub-licensed to Shionogi Co. Ltd and Dainippon Sumitomo Pharma Co. Ltd, respectively. Aprovel<sup>®</sup> U.S. market exclusivity is expected to be maintained through March 2012.

### **Alliance with Bristol-Myers Squibb (BMS)**

Plavix<sup>®</sup> and Aprovel<sup>®</sup> are marketed through a series of alliances with BMS. The alliance agreements include marketing and financial arrangements that vary depending on the country in which the products are marketed.

Three principal marketing arrangements are used in the BMS alliance:

*co-marketing*: each company markets the products independently under its own brand names;

*exclusive marketing*: one company has the exclusive right to market the products; and



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*co-promotion*: the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name.

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world excluding Japan. In Japan, Aprovel<sup>®</sup> has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd since June 2008. The BMS alliance does not cover rights to Plavix<sup>®</sup> in Japan; sales of Plavix<sup>®</sup> in Japan are consolidated by Sanofi.

In the territory under our operational management, the marketing arrangements are as follows:

we use the co-promotion system for most of the countries of Western Europe for Aprovel<sup>®</sup> and Plavix<sup>®</sup> and for certain Asian countries for Plavix<sup>®</sup>;

we use the co-marketing system in Germany, Spain and Greece for both Aprovel<sup>®</sup> and Plavix<sup>®</sup> and in Italy for Aprovel<sup>®</sup>; and

<sup>(1)</sup> *Plavix<sup>®</sup> market = oral platelet aggregants inhibitors.*

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we have the exclusive right to market Aprovel® and Plavix® in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel® in Asia, Scandinavia and Ireland.

In the territory under BMS operational management, the marketing arrangements are as follows:

we use the co-promotion system in the United States and Canada, where the products are sold through the alliances under the operational management of BMS;

we use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix® and Aprovel® and in Colombia only for Plavix®; and

we have the exclusive right to market the products in certain other countries of Latin America.

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we often sell the active ingredients for the products to BMS or associated entities.

The financial impact of our principal alliances on our financial position and income is significant, and is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances ; see also Item 3. Key Information D. Risk Factors Risks Relating to Our Business We rely on third parties for the marketing of some of our products for more information relating to risks in connection with our alliance agreements.

## **Multaq®**

Multaq® (dronedarone) is the most extensively studied anti-arrhythmic drug (AAD) in Atrial Fibrillation (AF) and has demonstrated a unique cardiovascular (CV) outcome benefit in the ATHENA study in addition to effective rhythm control in the EURIDIS and ADONIS studies.

Multaq® is a multichannel blocker with both rhythm (prevention of atrial fibrillation recurrences) and rate (decrease of ventricular rate) controlling properties and additional effects (anti-hypertensive, vasodilatory). It is the first and only anti-arrhythmic drug to have shown a significant reduction in cardiovascular hospitalization and death in patients with paroxysmal and persistent Atrial Fibrillation/Atrial Flutter as seen in the ATHENA study.

The landmark ATHENA trial is the only double-blind anti-arrhythmic study in patients with AF to have assessed morbidity-mortality. The study enrolled a total of 4,628 patients. In this trial, the efficacy and safety of Multaq® was evaluated in patients with AF/AFL or a recent history of these conditions. Multaq® 400mg twice a day, in addition to standard therapy, was shown to significantly reduce the risk of first cardiovascular hospitalization or death by 24% (p<0.001) when compared to placebo, meeting the study's primary endpoint. In a secondary analysis of the ATHENA trial, Multaq® significantly reduced the total number of hospital days versus placebo.

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Following reports in January 2011 of hepatocellular liver injury and hepatic failure in patients receiving Multaq<sup>®</sup>, including two post-marketing reports of acute hepatic failure requiring transplantation, Sanofi has collaborated with health authorities agencies to update prescribing information and include liver function monitoring. In Europe, EMA has then coordinated a review of all available data concerning the possible risks of liver injury associated with the use of Multaq<sup>®</sup> and their impact on its benefit-risk balance. The review was extended to include cardiovascular safety of Multaq<sup>®</sup> following premature termination of the PALLAS study (Permanent Atrial fibrillation outcome Study) in July 2011.

The PALLAS study, using dronedarone on top of standard therapy, was a randomized, double-blind, parallel-group, placebo-controlled study comparing the efficacy of dronedarone 400 mg twice-daily to placebo in patients with permanent AF, a population different from the population with non-permanent AF for which Multaq<sup>®</sup> is currently approved. The study was discontinued in July 2011 following recommendation from the study's Operations Committee and the Data Monitoring Committee which observed a significant increase in cardiovascular events in the dronedarone arm. The decision to terminate the study was not related to any hepatic adverse event.

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The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) confirmed in September 2011 that the benefits of Multaq® continue to outweigh the risks with a revised indication for the treatment of a limited, newly defined population of paroxysmal and persistent Atrial Fibrillation patients. Multaq® is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation. Due to its safety profile, Multaq® should only be prescribed after alternative treatment options have been considered and should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous episodes of heart failure.

The FDA approved a label update in December 2011 to ensure its use in the appropriate patient population, specifically in patients in sinus rhythm with history of paroxysmal or persistent atrial fibrillation (AF) and reinforcing warnings and precautions for use.

Multaq® has a convenient fixed dose regimen of twice daily 400 mg tablets to be taken with morning and evening meals. Treatment with Multaq® does not require a loading dose and it can be initiated in an outpatient setting.

Multaq® has been launched in 39 countries. The three leading countries for sales of Multaq® in 2011 were the United States, Germany and Spain.

## **Renagel® and Renvela®**

Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate) are oral phosphate binders used by chronic kidney disease (CKD) patients on dialysis to treat a condition called hyperphosphatemia, or elevated phosphorus levels, which is associated with heart and bone disease. Renvela® is a second generation, buffered phosphate binder.

In the United States, there are an estimated 395,000 dialysis patients, approximately 90% of whom receive a phosphate binder. There are an estimated 350,000 dialysis patients in the EU and 65,000 in Brazil. In the EU, Renvela® is also approved to treat CKD patients not on dialysis but who have very high blood phosphorus levels.

The principal markets for Renagel® are the United States, the EU and Brazil. The principal markets for Renvela®, which was first marketed in 2008, are the United States and the EU (launched in 2010). In 2011, new launches took place in Singapore, Malaysia, Thailand, Israel, Columbia, Panama and Switzerland.

We market Renagel® and Renvela® directly to nephrologists through Genzyme's employee sales force and distribute these products through wholesalers and distributors. In Japan and several Pacific Rim countries, Renagel® is developed and marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

The top five countries contributing to the sales of our Renal portfolio in 2011 were the U.S., Italy, France, the UK, and Brazil.

**Synvisc®/Synvisc-One®**

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis of certain joints. Synvisc® is a triple-injection product and Synvisc-One® is our next-generation, single-injection product. The principal viscosupplementation market is treatment of pain associated with osteoarthritis of the knee.

The principal markets for Synvisc® are the U.S., the EU, and Japan (where launch took place in December 2010). The principal markets for Synvisc-One® are the United States and the EU, markets in which Synvisc-One® was first approved in 2009 and 2007, respectively.

We market Synvisc® and Synvisc-One® through Genzyme's employee sales force directly to physicians, hospitals, and pharmacies. We distribute these products directly and through independent distributors. In Japan, Synvisc® is marketed and distributed by Teijin Pharma Limited.

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The top five countries contributing to Synvisc<sup>®</sup> and Synvisc-One<sup>®</sup> sales in 2011 were the U.S., Japan, Canada, France, and Germany.

### ***Other pharmaceutical products***

#### **Stilnox<sup>®</sup>/Ambien<sup>®</sup>/Myslee<sup>®</sup>**

Stilnox<sup>®</sup> (zolpidem tartrate) is indicated in the short-term treatment of insomnia. Stilnox<sup>®</sup> rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for a minimum of six hours, and it is generally well tolerated, allowing the patient to awaken with a reduced risk of impaired attention, decreased alertness or memory lapses throughout the day.

We have developed a controlled release formulation of zolpidem tartrate, marketed only in the United States under the brand name Ambien<sup>®</sup> CR.

Stilnox<sup>®</sup> is marketed in over 100 countries. It was launched in Japan under the brand name Myslee<sup>®</sup> in December 2000. Myslee<sup>®</sup> has been co-promoted jointly with Astellas since 2006. Myslee<sup>®</sup> is the leading hypnotic in Japan (source: IMS 2011).

Generic zolpidem tartrate has been available in Europe since 2004. In the United States, generics of the immediate release formulation of Ambien<sup>®</sup> have been available since 2007. Ambien<sup>®</sup> CR generics entered the U.S. market in October 2010. In Japan, competing generics of Myslee<sup>®</sup> are likely to enter the market in 2012.

#### **Allegra<sup>®</sup>/Telfast<sup>®</sup>**

Allegra<sup>®</sup> (fexofenadine hydrochloride) is a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and for the treatment of uncomplicated hives. It offers patients significant relief from allergy symptoms without causing drowsiness.

We also market Allegra-D<sup>®</sup> 12 Hour and Allegra-D<sup>®</sup> 24 Hour, anti-histamine/decongestant combination products with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms, including nasal congestion. Generics of most forms of Allegra<sup>®</sup>/Telfast<sup>®</sup> have been approved in our major markets, with the notable exception of Japan.

In March 2011, in the U.S., Allegra<sup>®</sup> family moved to over-the-counter (OTC) use in adults and children two years of age and older (see Consumer Health Care below).

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Allegra®/Telfast® is marketed in approximately 80 countries. The largest market for prescriptions of Allegra® is Japan. In Japan, competing generics of Allegra® may possibly enter the market in the second half of 2012 if the generic manufacturers get marketing approvals. Sanofi appealed at the IP High Court to defend two Allegra® use patents following their invalidation by the patent office (for more information see Item 8 Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings ).

### **Copaxone®**

Copaxone® (glatiramer acetate) is a non-interferon immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis. Copaxone® is available as a self-injectable pre-filled syringe storable at room temperature for up to one month.

This disease-modifying drug is characterized by an original and specific mode of action on multiple sclerosis. Clinical studies have shown that Copaxone® is more effective than placebo at two years, but also that it has a clinical efficacy over 15 years both in reducing relapses and progression of disability. A significant effect on lesions has also been confirmed by nuclear magnetic resonance imaging.

In 2009, the U.K. Medicine and Healthcare Regulatory Agency (MHRA) approved an expanded label for Copaxone® to include the treatment of patients with clinically isolated syndrome suggestive of multiple sclerosis.

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We have marketed Copaxone® outside the United States and Canada through our alliance with Teva. As of February 29, 2012 we no longer market or sell Copaxone®: on a country-by-country basis, we instead receive a payment of 6% on sales from Teva for a period of two years from the date of transfer (see Alliance with Teva below).

### **Alliance with Teva**

We in-licensed Copaxone® from Teva and marketed it until 2012 through an agreement with Teva, which was originally entered into in 1995, and has been amended several times, most recently in 2005.

Under the agreement with Teva, marketing and financial arrangements vary depending on the country in which the products are marketed.

Sales and distribution rights were returned to Teva in 2008 for the United States and Canada.

Outside the United States and Canada, there were two principal marketing arrangements:

*Exclusive marketing:* we had the exclusive right to market the product. This system was used in a number of European countries (Portugal, Italy, Greece, Finland, Denmark, Sweden, Norway, Iceland, Ireland, Luxembourg, Poland, Lichtenstein, Switzerland), as well as in Australia and New Zealand.

*Co-promotion:* the product was marketed under a single brand name. We used the co-promotion system in Germany, the United Kingdom, France, the Netherlands, Austria, Belgium, the Czech Republic and Spain.

Under the terms of our agreement, the Copaxone® business has been transferred to Teva over a period running from the third quarter of 2009 to February 29, 2012 depending on the country. Following the transfer, Sanofi will receive from Teva a royalty of 6% for a period of two years, on a country-by-country basis. In September 2009, the Copaxone® business was transferred to Teva in Switzerland and Lichtenstein. In 2010, the Copaxone® business was transferred to Teva in Poland, in the Czech Republic and in the United Kingdom. In 2011, the Copaxone® business was transferred to Teva in Norway, Germany, Austria, Portugal, and Sweden. In January and February 2012 the Copaxone® business was transferred to Teva in Denmark, the Netherlands, Belgium, France, Greece, Cyprus, Ireland, Italy, Spain, Australia, and New Zealand.

### **Tritace®/Triatec®/Delix®/Altace®**

Tritace® (ramipril) is an angiotensin converting enzyme (ACE) inhibitor indicated for the treatment of hypertension, congestive heart failure following or in the absence of acute myocardial infarction, and nephropathy. Tritace® is the only ACE inhibitor approved for the prevention of stroke, myocardial infarction and death in high-risk patients and has the broadest spectrum of indications among ACE inhibitors for the treatment of cardiovascular diseases.



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The combinations with diuretics (ramipril + hydrochlorothiazide) and calcium channel blockers (ramipril + felodipine) are available in Europe.

Tritace® is marketed in over 70 countries. A number of generics have received marketing authorization and have been launched since December 2001 in Europe.

### **Depakine®**

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years. Numerous clinical trials and long years of experience have shown that it is effective for all types of epileptic seizures and epileptic syndromes, and is generally well tolerated. Consequently, Depakine® remains a reference treatment for epilepsy worldwide.

Depakine® is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder and, in numerous countries, in the prevention of mood episodes. Depakine® is recommended as a first

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line treatment in these indications by international guidelines such as the guidelines of the World Federation of Societies of Biological Psychiatry Guidelines 2009, the Canadian Network for Mood and Anxiety Treatments 2009, and the British Association for Psychopharmacology 2009.

We provide a wide range of formulations of Depakine® enabling it to be adapted to most types of patients: syrup, oral solution, injection, enteric-coated tablets, Depakine® Chrono (a sustained release formulation in tablets) and Depakine® Chronosphere (sustained release formulation of Depakine® packaged in stick packs, facilitating its use by children, the elderly and adults with difficulties swallowing).

Depakine® is marketed in over 100 countries.

## **Xatral®/Uroxatral®**

Xatral® (alfuzosin hydrochloride) belongs to the class of alpha1-blockers. Capable of acting selectively on the lower urinary tract, it was the first alpha1-blocker indicated and marketed exclusively for the treatment of symptoms of benign prostatic hyperplasia (BPH). It is also the only alpha1-blocker indicated as an adjunctive therapy with catheterization for acute urinary retention, a painful and distressing complication of BPH.

Xatral® OD (extended release formulation) is active from the first dose, provides rapid and lasting symptom relief, and improves patient quality of life. Xatral® is the only alpha1-blocker showing no deleterious effect on ejaculation, as shown by the final results of the international ALF-LIFE trial. The once-daily formulation of Xatral® (branded Uroxatral® in the United States) has been registered in over 90 countries and is marketed worldwide, with the exception of Australia and Japan.

Generic alfuzosin became available in most European countries in 2009. Generics of the extended release formulation of alfuzosin became available in the U.S. in July 2011.

## **Actonel®/Optinate® /Acrel®**

Actonel® (risedronate sodium) belongs to the bisphosphonate class that helps prevent osteoporotic fractures.

Actonel® is the only osteoporosis treatment that reduces the risk of both vertebral and non-vertebral fractures in as little as six months. Actonel® also provides reduced risk of fracture at all key osteoporotic sites: vertebral, hip and non-vertebral sites, studied as a composite endpoint (hip, wrist, humerus, clavicle, leg and pelvis).

Actonel® is available in various dosage strengths and combination forms to better suit patient needs. Depending on dosage form, Actonel® is indicated for the treatment of post-menopausal osteoporosis, osteoporosis in men, or Paget's disease.

Actonel<sup>®</sup> is marketed in more than 75 countries through an alliance with Warner Chilcott see Note C.2 to our consolidated financial statements included at Item 18 of this annual report .

The contribution of this alliance on our financial position and income is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances . See Item 3. Key Information D. Risk Factors Risks Relating to Our Business We rely on third parties for the marketing of some of our products for more information relating to risk in connection with our alliance agreements.

#### **Nasacort<sup>®</sup>**

Nasacort<sup>®</sup>AQ Spray (NAQ) (triamcinolone acetonide) is an unscented, water-based metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium. Previously indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children six years of age and older, Nasacort<sup>®</sup> AQ received an additional approval for the seasonal and annual treatment of pediatric patients between the ages of two and five years from the FDA in September 2008. NAQ is an intranasal corticosteroid, which is recommended in treatment guidelines as first-line treatment for moderate to severe allergic rhinitis patients.

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Following a settlement of patent litigation, a competing generic triamcinolone acetonide has been sold in the United States since June 2011.

### **Main compounds currently in Phase II or III clinical development:**

In the Multiple Sclerosis field:

**Teriflunomide Aubagio** (orally active dihydroorotate dehydrogenase inhibitor, multiple sclerosis; Phase III). The dossier has been submitted in August 2011 in the U.S. and in January 2012 in Europe for the treatment of relapsing forms of multiple sclerosis as a monotherapy agent. Results of the first pivotal study, indicating that the product had an effect on disease activity in terms of relapse rate, disability progression and brain lesions with a favorable safety profile, were published in the NEJM in October 2011. In addition, a Phase III adjunctive therapy study (TERACLES) has been launched to define the additional efficacy and safety profile of teriflunomide, when added to background stable therapy with interferon (IFN-beta). This study follows on from the successful Phase II study which showed teriflunomide had an acceptable tolerability in adjunct to IFN-beta and demonstrated significant improvements of the disease as measured by magnetic resonance imaging (MRI).

**Alemtuzumab (Lemtrada)** Humanized monoclonal antibody targeting CD52 antigen abundant on the surface of B and T lymphocytes leading to changes in the circulating lymphocyte pool. Alemtuzumab targets patients with relapsing forms of Multiple Sclerosis (MS). The two Phase III studies demonstrating the safety and efficacy of alemtuzumab were completed in 2011. The first study, CARE-MS I, demonstrated strong and robust treatment effect on the relapse rate co-primary endpoint vs Rebif. The co-primary endpoint of disability progression (time to sustained accumulation of disability SAD) did not meet statistical significance. The second study, CARE-MS II, demonstrated that relapse rate and SAD were significantly reduced in MS patients receiving alemtuzumab as compared with Rebif. In both cases, safety results were consistent with previous alemtuzumab use in MS and adverse events continued to be manageable. The dossier is scheduled to be submitted to FDA review in the second quarter of 2012.

In the context of a business combination prior to the Sanofi takeover, Genzyme acquired in May 2009, from Bayer Schering Pharma A.G (Bayer), development rights and world marketing rights for alemtuzumab. Genzyme also acquired the rights for the products Fludara<sup>®</sup> and Leukine<sup>®</sup>. Alemtuzumab is already approved in oncology as the product Campath<sup>®</sup> (also acquired from Bayer). In exchange, Bayer was granted the right to co-promote Lemtrada on a global basis, as well as the right to receive contingent payments (for more information See Note D.1.1. to our consolidated financial statements included in this annual report at Item 18). In connection with the acquisition of Genzyme, Sanofi issued contingent value rights ( CVR ) entitling holders to cash payments upon the achievement of certain milestones, including regulatory approval of alemtuzumab for treatment of multiple sclerosis and on achievements of certain aggregate sales thresholds (see Item 10. Additional Information C. Material contracts The Contingent Value Rights Agreement. )

In the Ophthalmology field:

Sanofi acquired the French ophthalmology specialist Fovea in October 2009. Products in the pipeline include:

A Phase II eye-drop fixed dose combination of prednisolone acetate and cyclosporine A for the treatment of allergic conjunctivitis (**FOV1101**);

A Phase II eye-drop formulation of a bradykinin B1 receptor antagonist for the treatment of diabetic macular edema (**FOV2304**);

**FOV2302** was halted in December 2011 for toxicity reasons.

Oxford BioMedica entered into collaboration with Sanofi in April 2009 to develop novel gene-based medicines, utilizing LentiVector® gene delivery technology, for the treatment of ocular disease. The agreement covers four LentiVector®-based product candidates for different ophthalmologic indications such as wet age-related macular degeneration, Stargardt disease, Usher syndrome, and corneal graft rejection.

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In the Thrombosis and Cardiovascular field:

**Otamixaban** (direct factor Xa inhibitor, interventional cardiology; Phase III). Otamixaban is an injectable, selective direct inhibitor of coagulation factor Xa. It is a synthetic small molecule. Otamixaban exhibits a fast on- and off-set of action. A Phase III program to confirm the positive outcome from the SEPIA-ACS Phase II study was initiated in 2010 and is now ongoing; results are expected for 2013.

**Celivarone** (anti-arrhythmic; Phase IIb): project terminated because of lack of efficacy (prevention of shocks and major clinical outcomes) in the Phase II study in patients fitted with an implantable cardioverter/defibrillator.

In the Internal Medicine field:

**Sarilumab (SAR153191)**, a monoclonal antibody against the Interleukin-6 Receptor (anti IL-6R mAb) derived from our alliance with Regeneron, entered in Phase III in adult patient with moderate to severe rheumatoid arthritis.

**SAR231893**, a monoclonal antibody against the Interleukin-4 Receptor (anti IL-4R mAb) derived from our alliance with Regeneron, has entered Phase IIa in asthma and continued development in Phase I in atopic dermatitis.

**Mipomersen** (Genzyme) Antisense oligonucleotide (ASO) that inhibits the synthesis of apoB, a primary protein constituent of atherogenic lipoproteins. In collaboration with Isis Pharmaceuticals Inc. mipomersen is being developed for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) and severe heterozygous FH (HeFH). FH is a genetic disorder that causes chronic and lifelong exposure to markedly elevated concentrations and numbers of atherogenic, apoB-containing lipoproteins (LDL, Lp(a)) leading to premature and severe cardiovascular disease. The marketing authorization application (MAA) for mipomersen was submitted in the third quarter of 2011 in Europe.

## **Consumer Health Care (CHC)**

Consumer Health Care is a core growth platform identified in our broader strategy for achieving sustainable growth. In 2011, we recorded CHC sales of 2,666 million; nearly half of our CHC sales were in emerging markets, 24% in Europe, and 21% in the United States.

In March 2011, the Allegra® family of allergy medication products was commercially launched in the U.S. for over-the-counter (OTC) use in adults and children two years of age and older. The Allegra® family of OTC products is available in drug, grocery, mass merchandiser, and club stores nationwide. This switch constitutes a key step in our CHC growth strategy in the U.S. The Allegra® family of OTC products is the number one OTC brand for Sanofi globally.

2011 CHC sales were also supported by our legacy CHC brands, which provides us with a strong presence in the fever & pain and digestive health areas.

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Doliprane® is a range of paracetamol formulas to fight pain and fever. Thanks to a wide offer both in terms of dosages (from 2.4% paracetamol suspension up to 1g formulas) and pharmaceutical forms (suspension, tablets, powder, suppositories), Doliprane® covers the needs of the patients from baby to elderly. Doliprane® is sold mainly in France and in some African countries.

NoSpa® is a product containing drotaverine hydrochloride. NoSpa® is indicated in abdominal spastic pain such as intestinal spasm, menstrual pain, or vesical spasm. NoSpa® is sold mainly in Russia and Eastern Europe.

Enterogermina® is composed of two billion *Bacillus clausii* spores in a ready-to-drink oral suspension in vials of 5ml and in capsules. Enterogermina® is indicated in the prevention and the treatment of intestinal imbalance during acute or chronic intestinal disorders (from babies to adults). Enterogermina® is sold mainly in Europe and has been enjoying strong growth in Latin America, India and Central Asia.

Essentiale® is a herbal preparation for liver therapy, made of highly purified essential phospholipids extracted from soybeans and containing a high percentage of phosphatidylcholine, a major constituent

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of cellular membrane. Essentiale® is used to treat symptoms such as lack of appetite, sensation of pressure in the right epigastrium, toxico-nutritional liver damage and hepatitis. Essentiale® is sold mainly in Russia, Eastern Europe, and some South East Asian countries.

Maalox® is a well-established brand containing two antacids: aluminium hydroxide and magnesium hydroxide. Maalox® is available in several pharmaceutical forms – tablets, suspension, and stick packs – to provide consumer choice. Maalox® is present in 55 countries: in Europe, Latin America, Russia, Africa, Middle East, and in some Asian countries.

Magne B6® is a product containing magnesium and vitamin B6. MagneB6® has various therapeutic indications from irritability, anxiety and sleep problems to women's health issues like premenstrual syndrome or menopause discomfort. MagneB6® is present in Europe and Russia.

Lactacyd® is a range of products for feminine hygiene. Lactacyd® is sold mainly in Brazil and Asia. Lactacyd® was launched in China in May 2011.

Complementary to our legacy CHC business, well-known brands are:

Chattem's products in the United States, other than the Allegra® family of OTC products, are mainly branded consumer healthcare products, toiletries and dietary supplements across niche market segments. Chattem's well-known brands include Gold Bond®, Icy Hot®, ACT®, Cortizone-10®, Selsun Blue® and Unisom®.

Enobiol's products in France are dietary supplements for beauty (sun care, weight, hair care, skin care); well-being (digestive comfort, anti-stress) and menopausal problems.

BMP Sunstone products in China include leading pediatric cough and cold brand, Haowawa® (which means "Goodbaby" in Chinese). BMP Sunstone also brings Sanofi a very well-established national distribution network providing unique access to the fast-growing prefecture level and rural level cities.

Minsheng products in China include 21 Super Vita, one of the leading vitamins & mineral supplements.

In August 2011, we entered into a definitive agreement to acquire the Indian domestic branded formulations business of Universal Medicare, one of the leading providers in the country of nutraceuticals and lifestyle management products including vitamins, antioxidants, mineral supplements, and anti-arthritis.

The top three countries contributing to our CHC sales in 2011 were the United States, France, and Russia.

## **Generics**

In 2011, sales of the generics business grew by 16.2% to 1,746 million led by sales in Emerging Markets and in the United States. U.S. generic business growth was driven by sales of recent launches of authorized generics of Taxotere®, Ambien® CR and Lovenox®. Authorized generic of



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Taxotere® launched in March 2011 has captured more than 10% of docetaxel generics (source: IMS December 2011). Sales in Emerging Markets were supported by the roll out of Medley products in additional countries in Latin America. In 2011, sales of generic products in Emerging Markets exceeded 1 billion. See Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010 Net Sales by Product Pharmaceuticals .

In March 2009 we created our European Generics Platform, covering generics activities across Western and Eastern Europe, Russia and Turkey. In 2010, we decided to rebrand all our European generics businesses under the Zentiva name. This means that the generics businesses of Winthrop and Helvepharm in France, Germany, Italy, Switzerland, Portugal and the United Kingdom now operate under the Zentiva brand. The roll out will continue in 2012 in the EU countries where Zentiva operates.

In Japan in 2011 we established a new joint venture, Sanofi Nichi-Iko K.K., to develop a strong presence in the fast-growing Japanese generics market: we started co-promotion for two molecules (edaravone in August 2011 and donepezil in October 2011). Scope of products to be co-promoted should be expanded in the future.

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### Vaccine Products

Sanofi Pasteur is a fully integrated vaccines division offering a broad range of vaccines. In 2011, Sanofi Pasteur provided more than 1 billion doses of vaccine, making it possible to immunize more than 500 million people across the globe against 20 serious diseases and generated net sales of \$3,469 million. Sales were favorably impacted by strong growth in markets outside North America and Europe, continued growth of Pentaxim® sales and successful seasonal influenza vaccine campaigns in both the Northern and Southern hemispheres. See Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010 Net Sales Human Vaccines (Vaccines).

Sanofi Pasteur is a world leader in the vaccine industry in terms of sales. In the United States, Sanofi Pasteur is the market leader in the segments where we compete (source: based on internal estimates).

In Europe, Sanofi Pasteur vaccine products are developed and marketed by Sanofi Pasteur MSD, a joint venture created in 1994 and held equally by Sanofi Pasteur and Merck & Co. Inc., which serves 19 countries. Sanofi Pasteur MSD also distributes such Merck & Co. vaccine products as Gardasil® in the joint venture's geographic scope. In 2011, Sanofi Pasteur MSD net sales, which are accounted for using the equity method, amounted to \$791 million.

Sanofi Pasteur has been expanding in Asia (China, India and Japan), Latin America (Mexico and Brazil), Africa, the Middle-East and Eastern Europe. Sanofi Pasteur is very active in publicly-funded international markets such as UNICEF and the Global Alliance for Vaccines and Immunization (GAVI).

The table below shows net sales of vaccines by product range:

	<b>2011</b>
( \$ million)	<b>Net Sales</b>
Influenza Vaccines *	826
Polio/Pertussis/Hib Vaccines	1,075
Meningitis/Pneumonia Vaccines	510
Adult Booster Vaccines	465
Travel and Other Endemics Vaccines	370
Other Vaccines	223
<b>Total Human Vaccines</b>	<b>3,469</b>

\* Seasonal and pandemic influenza vaccines.

### Pediatric Combination and Poliomyelitis (Polio) Vaccines

These vaccines vary in composition due to diverse immunization schedules throughout the world.

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Sanofi Pasteur is one of the key players in pediatric vaccines in both emerging and mature markets with a broad portfolio of standalone and combination vaccines protecting against up to five diseases in a single injection.

Pentacel<sup>®</sup>, a vaccine protecting against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b), was launched in the United States in 2008.

Pediacel<sup>®</sup>, a fully liquid acellular pertussis-based pentavalent vaccine, is the standard of care in the United Kingdom since 2004 for protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b disease. As of December 31, 2011, Pediacel<sup>®</sup> was approved in 29 countries across Europe in a new syringe presentation.

Pentaxim<sup>®</sup>, a combination vaccine protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b was first marketed in 1997 and was launched in China in May 2011. To date, more than 100 million doses of Pentaxim<sup>®</sup> have been distributed in over 100 countries, and the vaccine has been included in the national immunization programs in 23 countries.

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Act-HIB<sup>®</sup>, for the prevention of *Haemophilus influenzae* type b (Hib) infections, is also an important growth driver within the pediatric product line. In 2008, Act-HIB<sup>®</sup> became the first Hib vaccine to be approved in Japan.

Hexaxim<sup>™</sup>, is a hexavalent pediatric vaccine providing protection against diphtheria, tetanus, pertussis, poliomyelitis (polio), *Haemophilus influenzae* type b infections and hepatitis B. The vaccine is currently under the registration process (Article 58) at EMA, with an opinion expected in 2012.

PR5I is a combination vaccine designed to help protect against six potentially serious diseases: diphtheria, tetanus, whooping cough (pertussis), polio (poliovirus type 1, 2 and 3), invasive disease caused by *Haemophilus influenzae* type b, and hepatitis B. This product is jointly being developed between Sanofi Pasteur and Merck in the U.S. and Europe. Phase III studies in the U.S. and Europe began in April 2011.

Sanofi Pasteur is one of the world's leading developers and manufacturers of polio vaccines, both oral (OPV) and enhanced injectable (eIPV) form. The worldwide polio eradication initiative led by the World Health Organization (WHO) and UNICEF has positioned Sanofi Pasteur as a global preferred partner with both OPV and eIPV vaccines.

In September of 2011, Sanofi Pasteur donated to the WHO a vaccine strain used for polio eradication. The biological material given by Sanofi Pasteur is the original viral seed used to produce large quantities of OPV against type 3 poliovirus. With this donation from Sanofi Pasteur, the WHO will be in full control of the storage of the vaccine strain and its distribution to vaccine producers worldwide.

Sanofi Pasteur is also supporting the introduction of eIPV in the international region. With recent progress towards polio eradication, Sanofi Pasteur expects the use of eIPV to gradually increase. As a result, Sanofi Pasteur is expanding its production capacity to meet the growing demand.

On February 23, 2011, Sanofi Pasteur applied for approval of manufacturing and marketing of standalone inactivated vaccine against polio (acute poliomyelitis) in Japan.

Shantha Biotechnics is currently pursuing requalification of Shan5<sup>®</sup>, a combination vaccine protecting against diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae* type b with the WHO. Shantha has worked closely with Sanofi Pasteur to improve key manufacturing steps in the production of the antigen components of the vaccine. The path back to obtaining Prequalification status has been discussed extensively with the WHO and local Indian regulators. Based on the successful completion of clinical studies, Shan5<sup>®</sup> is expected to regain WHO prequalification in 2014.

## **Influenza Vaccines**

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines. Sales of the influenza vaccines Fluzone<sup>®</sup> and Vaxigrip<sup>®</sup>/Mutagrip<sup>®</sup> have more than tripled since 1995 and annual supply reached more than 200 million doses in 2011 to better meet increasing demand. In recent years, influenza vaccine demand has experienced strong growth in many countries, particularly in the U.S., South

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Korea, Brazil and Mexico. Sanofi Pasteur expects the global demand for influenza vaccines to continue to grow within the next decade due to increased disease awareness, growth in emerging markets and wider government immunization recommendations.

Sanofi Pasteur remains focused on maintaining its leadership in the influenza market and on meeting the increasing demand for both pandemic and seasonal influenza vaccines through the launch of innovative vaccines.

In May 2011, Sanofi Pasteur received regulatory approval by the U.S. FDA for Fluzone® ID in adults from 18 to 64 years of age. The advantages of this vaccine are particularly its convenience and ease of administration. Fluzone ID®, Intanza®/IDflu® vaccine is now approved in the United States, European Union, Canada, Australia and other countries for the prevention of seasonal influenza in both adults (age 18 and over) and the elderly (age 60 and over).

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In December 2009, the FDA approved Sanofi Pasteur's supplemental Biologics License Application (sBLA) for licensing of Fluzone<sup>®</sup> High-Dose influenza virus vaccine. The Fluzone<sup>®</sup> High-Dose vaccine was specifically designed to generate a more robust immune response in people 65 years of age or older. This age group, which typically shows a weaker immune response, has proven to respond better to the Fluzone<sup>®</sup> High-Dose vaccine. This new vaccine was launched in the United States in 2010 and continued strong growth in 2011.

Fluzone<sup>®</sup> QIV candidate vaccine is a quadrivalent inactivated influenza vaccine containing two antigens of type A (H1N1 and H3N2) and two antigens of type B (one each from Yamagata and Victoria lineage). Selecting the prevailing influenza strains for upcoming seasons is an incredibly difficult task. In the recent past, there have been a number of mismatches of the B strain component in the trivalent vaccine compared with the circulating B lineage. Sanofi Pasteur expects that increasing the number of strains in the vaccine will give increased protection against the most prevalent strains. The targeted population is the same as standard-dose Fluzone<sup>®</sup> TIV (trivalent vaccine): children 6 months through 17 years, and adults and elderly 18 years and above. A Phase III clinical trial was completed in 2011 for Fluzone QIV IM and regulatory submission is planned for the first half 2012. Vaxigrip QIV IM, targeting the European market, entered Phase III clinical trials in October 2011.

### **Adult and Adolescent Boosters**

Pertussis (whooping cough) affects children, adolescents and adults. Resurgence, in particular in the State of California in the U.S. and other parts of the world in 2010, combined with increased awareness of the dangers of vaccine-preventable diseases in general, has led to higher sales of this product group in recent years. Adacel<sup>®</sup>, the first trivalent adolescent and adult booster against diphtheria, tetanus and pertussis, was licensed and launched in the United States in 2005. Since 2004, Adacel<sup>®</sup> has been the standard of care in Canada, where most provinces provide routine adolescent immunization. This vaccine plays an important role in efforts to better control pertussis, by preventing the disease in adolescents and adults, and by breaking the cycle of transmission to infants too young to be immunized or only partially vaccinated. Adacel<sup>®</sup> is now registered in more than 50 countries.

Quadracel<sup>®</sup>, a quadrivalent booster vaccine (fifth dose) including diphtheria, tetanus, acellular pertussis and IPV is being developed for the U.S. market. It would allow a child to complete the entire childhood series with the fewest doses possible. A Phase III clinical trial began in April 2011.

### **Meningitis and pneumonia vaccines**

Sanofi Pasteur is at the forefront of the development of vaccines to prevent bacterial meningitis. In 2005, Sanofi Pasteur introduced Menactra<sup>®</sup>, the first conjugate quadrivalent vaccine against meningococcal meningitis, arguably the deadliest form of meningitis in the world. In October 2007, the FDA granted Sanofi Pasteur a license to expand the indication of Menactra<sup>®</sup> to children two years through 10 years of age. Menactra<sup>®</sup> is now indicated for people aged 2-55 years in the United States and in Canada. In 2011, sales of Menactra<sup>®</sup> continued to grow in the United States following the CDC's Advisory Committee on Immunization Practices recommendation that a single dose at 11 or 12 years of age be followed-up with a booster dose several years later for protecting adolescents at the time of their highest risk. An Infant/Toddler (age 9/12 months) biological license application for Menactra<sup>®</sup> was approved by the U.S. FDA in March 2011. Sanofi Pasteur also launched Menactra<sup>®</sup> in the Middle East and Latin America in 2010 and in Asia in 2011.

Meningitis A, C, Y, W-135 conj. Second Generation is a project that targets a second generation meningococcal vaccine that uses an alternative conjugation technology. In 2011, interim Phase II clinical trial results were obtained and indicated that the product is sufficiently immunogenic for further development in infants.

For over 30 years, Sanofi Pasteur has supplied vaccines for meningococcal meningitis serogroups A and C used to combat annual epidemics in Sub-Saharan countries (African meningitis belt).

**Travel and Endemics Vaccines**

Sanofi Pasteur provides a wide range of travelers and endemic vaccines with hepatitis A, typhoid, rabies, yellow fever, cholera measles, mumps, rubella (MMR) vaccines and anti-venoms. These vaccines are used in

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endemic settings in the developing world and are the basis for important partnerships with governments and organizations such as UNICEF. They are also used by the military and travelers to endemic areas. As the global leader in the majority of these vaccine markets, Sanofi Pasteur's Travel/Endemics activity has demonstrated stable growth.

A Japanese encephalitis vaccine is also in preparation. Japanese encephalitis is endemic in Southeast Asia. Sanofi Pasteur will offer a new vaccine in the market: IMOJEV™. The Australian healthcare authorities granted approval of IMOJEV™ on August 16, 2010 for individuals aged 12 months and over. On October 29, 2010, the Thai Food and Drug Administration granted licensure in the same age indication.

The new generation Vero serum-free vaccine (VRVg) will provide a worldwide, single rabies vaccine as a replacement to our current rabies vaccine offerings. Results from the 2009 Phase I clinical trial demonstrated non-inferiority of VRVg versus Verorab®. AFSSAPS in France approved VRVg as a line extension of VeroRab in January 2011. Clinical development is continuing in China and India.

In December 2009, Shantha launched ShanChol™, India's first oral vaccine to protect against cholera in children and adults. In September 2011, Shanchol™ was approved for procurement to United Nations Agencies (i.e. WHO Pre-qualified).

## **Other Products**

In October 2011, Sanofi Pasteur acquired Topaz Pharmaceuticals, Inc., a small privately-held U.S. specialty pharmaceutical company focused on developing and commercializing treatments primarily for pediatric and dermatology markets. Established in June 2005 and based in Horsham PA, Topaz Pharmaceuticals offers a late-stage prescription product for the treatment of head lice. This investigational product, known as Sklice, Topical Lotion, is a formulation of Ivermectin. It is the sole pipeline product of the company. The regulatory submission for Sklice, topical Lotion, for treatment of head lice in children and adults, was filed with the U.S. FDA in April 2011. In February 2012, the FDA approved Sklice® (ivermectin) lotion, 0.5% for the topical treatment of head lice, in patients 6 months of age and older.

## **Animal Health: Merial**

Our animal health activity is carried out through Merial, one of the world's leading animal healthcare companies (source: Vetnosis), dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners. It provides a comprehensive range of products to enhance the health, well-being and performance of a wide range of animals (production and companion animals). Its net sales for 2011 amounted to 2,030 million.

Merial became Sanofi's dedicated animal health division following the joint statement issued by Merck and Sanofi in March 2011 announcing the end of their agreement to create a new animal health joint venture by combining their respective animal health segments. Consequently all Merial financials are consolidated in Group reports. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report.



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The animal health product range comprises four major segments: parasiticides, anti-infectious drugs, other pharmaceutical products (such as anti-inflammatory agents, anti-ulcerous agents, etc.) and vaccines. Merial's top-selling products include Frontline®, a topical anti-parasitic flea and tick brand for dogs and cats, the highest selling veterinary product in the world (source: Vetnosis 2011); Heartgard®, a parasiticide for control of heartworm in companion animals; Ivomec®, a parasiticide for the control of internal and external parasites in livestock; Vaxxitek®, a high-technology vector vaccine, protects chickens against infectious bursal disease (IBD) and Marek's disease; Previcox®, a highly selective anti-inflammatory/COX-2 inhibitor for relief of pain and control of inflammation in dogs; Eprinex®, a parasiticide for use in cattle; and Circovac® a PCV2 (porcine circovirus type 2) vaccine for swine. Merial plays a key role in the veterinary public health activities of governments around the world. It is the world leader in vaccines for Foot-and-Mouth disease (FMD); rabies, and bluetongue (BTV) (source: Vetnosis 2011).

The compound patent protecting fipronil, the active ingredient of Frontline®, expired in 2009 in Japan and in some European countries, including France, Germany, Italy, and the United Kingdom, and in August 2010 in the United States. In those markets where the fipronil compound patent has expired, Frontline® products are generally still protected through formulation patents (directed to combinations) which expire at the latest in 2017.

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in Europe (August 2016 in the United States). Frontline® is also protected by a method of use patent in the United States and the European Patent area (Germany, France, Italy and the United Kingdom), expiring March 2018. As for human pharmaceutical products, patent protection for animal pharmaceutical products extends in most cases for 20 years from the filing date of the priority application.

As regards regulatory exclusivity, the position of veterinary medicinal products in Europe is similar to that of human pharmaceutical products: eight-year data exclusivity and ten-year market exclusivity. In the United States, there is ten-year data exclusivity for products approved by the Environmental Protection Agency and an additional five years during which a generic applicant has to compensate the originator if it cites the originator's data. For FDA approved veterinary medicinal products, a regulatory exclusivity period of five years is granted for a new chemical entity and three years for a previously-approved active ingredient. No data exclusivity exists at present for veterinary vaccines in the United States.

Regarding companion animals and specially the fipronil franchise, on June 21, 2011 the U.S. District Court for the Middle District of Georgia ruled in favor of Merial holding that sales of PetArmor Plus products infringed Merial's patent, and it barred Cipla and Velcera from making or selling those products in the United States. A court-ordered seizure of the inventory in the United States still in possession of the generic manufacturers went into effect on August 21, 2011. However, the generic products already sold to retailers were not recalled (see Item 8. Financial Information - A. Consolidated Financial Statements and Other Financial Information). In July 2011, Merial launched Certifect, a new fipronil combination parasiticide for tick and flea control for dogs.

Regarding production animals, in the ruminant segment, performance was driven by the launch in the U.S. of the antibiotic Zactran® against bovine respiratory disease.

Merial's major stand-alone markets are the United States, France, Brazil, Italy, the United Kingdom, Australia, Germany, Japan, Spain, China, and Canada. The group of Emerging Markets countries, with double digit sales growth in 2011, accounts now for 25.0% of total Merial sales.

Merial operates through a network of 16 production sites, with major sites located in France, the United States, Brazil and China. The major R&D sites are located in France and in the United States. Merial employs approximately 5,600 employees worldwide.

## **Pharmaceutical Research & Development**

The pharmaceutical industry as a whole has been facing significant challenges in the recent years.

These include:

Patent cliff for several products considered as blockbusters, putting revenues under pressure and increasing competition of me-too drugs,

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Decrease in New Molecular Entities approvals by Health Authorities (a 50% drop when compared to the 1990 s),

Increasing regulatory requirements and payers demands for demonstrated medical and economic value impacting the costs of development

Increased complexity of science leading to a decrease in the success rate for research projects.

To overcome this new situation, Sanofi has revised its overall infrastructure and operations footprint and opened up to external innovation and new fields of opportunity, so as to feed and strengthen its pipeline. We have adopted a network-based organization, open to external opportunities, to enable our R&D to be more creative and make the most of both in-house and external innovation. In December 2011, out of 48 products in clinical development or registration, 34 (or 71%) originate from external R&D. Employee year-end headcount in the research and development functions generally reflects this trend to greater externalization, and amounted to 18,823 for 2011 compared to 16,983 for 2010 and 19,132 for 2009 (in each case excluding Merial but including Genzyme in 2011 - 2,006 employees).

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We intend to have the most effective R&D organization in the pharmaceutical industry in place by 2013. The new R&D approach aims to foster greater creativity and innovation. Streamlined organizational structures are designed to make R&D more flexible and entrepreneurial and hence better adapted to overcome future challenges.

### **Organization**

During the first phase of transformation (2009-2011) we carried out a rigorous and deep re-evaluation of all current development programs. As a result, we have refocused our efforts on 48 clinical programs (see table below).

In parallel we undertook a profound transformation of our operating model reinforcing our patient centric approach and setting an open innovation strategy.

Decentralization with the creation of Oncology, Diabetes and Ophthalmology divisions, five Therapeutic strategic units (TSUs), several Distinct Project Units (DPUs) and five Scientific platforms.

A renewed effort at business development to fill the pipeline by acquiring or in-licensing products which has led to a series of acquisitions.

In line with the Group's diversification strategy, acquisition of Genzyme in April 2011 leading to a push in biotechnology and bringing the Group's goal of building a globally integrated R&D organization a step closer.

With Sanofi Pasteur, Genzyme and Merial, targeted initiatives launched internally to best leverage each other's knowledge and experience and establish a governance model to foster effective collaboration and innovation between all organizations.

Creation of alliances with premier academic programs in the U.S., Europe and a major effort in France with the Aviesan program.

### **Portfolio**

During 2011, R&D followed up the rigorous and comprehensive portfolio review already initiated in 2009. Projects were assessed using seven key criteria which allow management to rapidly understand how the portfolio performs in terms of innovation, unmet medical needs, risk and value. They can be summarized as follows:

science: level of innovation, level of safety, quality and reliability of the scientific data;

pharmacovigilance: assessment of the benefit/risk ratio for products (i.e., the clinical benefit versus the potential side effects).

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execution: likelihood of development and manufacturing success;

market: existence of a market, positioning within this market, and our place in the market;

reimbursement: likelihood of achieving the desired price and reimbursement based on the health authorities positioning and Sanofi competencies;

regulatory/legal: dealing with the environment around the project, patent status, regulatory guidelines; and

financial: predicted return on investment for the project.

At the end of 2011, the current clinical portfolio is the result of decisions taken during these reviews, plus compounds entering the portfolio from the discovery phase or from third parties through acquisition, collaboration or alliances.

As described at Item 3. Key Information D. Risk Factors Risks Relating to Our Business We may fail to adequately renew our product portfolio whether through our own research and development or through acquisitions and strategic alliances. our product development efforts are subject to the risks and uncertainties inherent in any new product development program.

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The clinical portfolio for new medical entities can be summarized as follows:

	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III /registration</b>
Diabetes	SAR164653	SAR236553	Lixisenatide
Oncology	SAR407899		
	SAR125844	SAR245408 (XL147)	aflibercept (AVE005)
	SAR153192	SAR245409 (XL765)	ombrabulin (AVE8062)
	SAR307746	SAR256212 (MM-121)	SAR240550 (BSI-201)
	SAR566658	SAR3419	SAR302503
	SAR650984		semuloparin (AVE5026)
Ophthalmology	Genz-644282		
	GC1008 RetinoStat®	FOV1101	
	StarGen	FOV2304	
Genzyme	sFLT-01 AAV AAV-AADC		alemtuzumab
	rhASM		mipomersen
	Fresolimumab		eliglustat tartrate
TSU Aging	SAR114137	SAR110894	
	SAR292833	SAR113945	
		SAR164877	
TSU Fibrosis & Wound Repair	SAR100842		
	SAR156597		
TSU Infectious Diseases		Ferroquine	
		SAR97276	
TSU Immuno-Inflammation DPU's	SAR339658	SAR279356	
	SAR126119	SAR231893	otamixaban
	SSR411298		teriflunomide
			sarilumab (SAR153191)

Phase I studies are the first studies performed in humans, in healthy volunteers. Their main objective is to assess the tolerability, the pharmacokinetic profile (the way the product is distributed and metabolized in the body and the manner by which it is eliminated) and where

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possible the pharmacodynamic profiles of the new drug. (how the product may react on some receptors)

Phase II studies are early controlled studies in a limited number of patients under closely monitored conditions to show efficacy and short-term safety and to determine the dose and regimen for Phase III studies.

Phase III studies have the primary objective of demonstrating or confirming the therapeutic benefit and the safety of the new drug, in the intended indication and population. They are made to provide an adequate basis for registration.

The Phase II & III compounds are described in the section **Pharmaceutical Products** **Main Pharmaceutical Products** above. A table summarizing selected key facts concerning our late stage experimental pharmaceutical products follows, at the end of this section.

The remainder of this section focuses on Phase I compounds entries, and lists projects that were terminated in 2011.

### **Diabetes/Other Metabolic Disorders portfolio**

**SAR164653**, an inhibitor of Cathepsin A, entered Phase I development. The product is being developed to prevent heart failure for patients having experienced acute coronary syndromes.

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A new formulation of insulin glargine has been tested in Phase I. This new product shows an improved pharmacodynamic profile. Phase III investigating the efficacy and safety in a broad patients population has been initiated end of 2011.

**Lantus:** the Lantus Pediatric Investigational plan was finalized as scheduled and results have been submitted in Europe in time.

The development of **SAR101099**, an Urotensin II Receptor Antagonist, has been discontinued.

## **Oncology portfolio**

**With the acquisition of Genzyme in April 2011, the following compounds have reinforced Sanofi Phase I pipeline.** Thus, in addition to the marketed intravenous formulation of clofarabine, a potent DNA synthesis inhibitor already registered for pediatric ALL, an oral formulation of the same active ingredient is being developed in new hematological malignancies indications. Also, GENZ-644282, a non-camptothecin topoI inhibitor, and GC 1008, an anti-TGF $\beta$  monoclonal antibody, are being developed in solid tumors.

**Furthermore, SAR307746 (REGN910)**, a monoclonal antibody directed against Ang2 issued from the partnership with Regeneron, entered Phase I in oncology in the first quarter of 2011.

**Finally, the global development of SAR103168**, a Phase I multikinase inhibitor being developed in AML, **was halted** due to pharmacokinetic considerations

## **Genzyme portfolio**

**rhASM** Enzyme replacement therapy targeting the treatment of Niemann-Pick B disease. A Phase II study is under preparation.

**Fresolimumab** TGF- $\beta$  antagonist targeting the treatment of Focal Segmental Glomerulosclerosis (FSGS). Preparations for Phase II took place in 2011.

**AAV-AADC** Gene therapy based on AAV vector targeting the treatment of moderate to severe Parkinson's disease. The low-dose cohort of the Phase I study is completed and follow-up is ongoing.

## **Ophthalmology portfolio**

A number of compounds for the treatment of eye disease were added to the portfolio via the acquisition of Fovea, the collaboration agreement with Oxford BioMedica and the acquisition of Genzyme (see Pharmaceutical Products Main Pharmaceutical Products Other Pharmaceutical Products above).



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In gene therapy, three compounds targeting the treatment of Age-related Macular Degeneration (AMD) and Stargardt Disease entered into Phase I in 2011

- RetinoStat® (AMD) gene therapy based on Lentivector
- sFlt01 (AMD) gene therapy based on AAV vector
- Stargen (Stargardt disease) gene therapy based on Lentivector

### TSU Aging portfolio

Two compounds have progressed into Phase II clinical development:

**SAR110894** (H3 receptor antagonist for the treatment of Alzheimer's dementia)

**SAR113945** (IKK- $\beta$  kinase inhibitor for the treatment of osteoarthritis by intra-articular administration)

1 compound has completed a Phase I program and should enter Phase II in 2012

**SAR292833** GCR-15300, licensing agreement with Glenmark Pharmaceutical (TRPV3 antagonist for the oral treatment of chronic pain)

## **Table of Contents**

1 compound recently completed a Phase I program results analysis on-going:

**SAR114137** (Cathepsin S/K inhibitor for the oral treatment of chronic pain)

1 compound will enter Phase I clinical development in the first quarter of 2012:

**SAR228810** (anti-protofibrillar AB mAb for the treatment of Alzheimer's dementia)

1 compound has been terminated:

**SAR152954** (H3 receptor antagonist)

In 2011, two key research agreements were signed with Audion Therapeutics and Aviesan to develop potential treatments in hearing loss and hearing disorders.

### **For Discovery/development partnerships:**

In-license agreement signed in December 2011 with SCIL Technology GMBH, a German biopharmaceutical company to develop CD-RAP products in osteoarthritis indication.

Opt-in agreement signed with Regeneron in December 2011 to develop an anti-GDF8 mAb in the sarcopenia indication

### **TSU Infectious Diseases portfolio**

**Ferroquine** (4-aminoquinoline; malaria; Phase IIb). Ferroquine is a new 4-amino-quinoline being developed for the treatment of acute uncomplicated malaria. Ferroquine is active against chloroquine sensitive and chloroquine resistant Plasmodium strains, and due to its long half-life has the potential to be part of single dose cure regimens and the unified global treatment of both vivax and falciparum malaria.

**SAR279356** (first-in-class human monoclonal antibody for the prevention and treatment of *S. aureus*, *S. epidermidis*, *E. coli*, *Y. pestis* and other serious infections) The option to acquire an exclusive and worldwide license from Alopexx Pharmaceuticals LLC for the development and commercialization of SAR279356 was exercised in October 2010. Phase I was successfully completed in early 2011 and a Phase II PK/PD study started in the third quarter of 2011 is ongoing.

**SAR97276** (in licensed from CNRS) is an antimalarial drug belonging to a new chemical class with an innovative mechanism of action, being developed for the treatment of severe malaria. A Phase IIa study started in the third quarter of 2011.

### **TSU Immuno-Inflammation portfolio**

**SAR339658** (also known as GBR500), a monoclonal antibody directed at the VLA-2 (Very Late Antigen 2) integrin receptor was in-licensed from Glenmark Pharmaceuticals in May 2011. The primary target indication is inflammatory bowel disease such as ulcerative colitis or Crohn's disease. The compound successfully completed Phase I in 2010 and is on track to enter Phase II in 2012.

#### **Other Projects portfolio**

The Phase I program for **SAR126119**, an injectable synthetic inhibitor of TAFI (thrombin-activable fibrinolysis inhibitor) has been conducted successfully. The Phase II study in the treatment of acute ischemic stroke (AIS), is expected to start in 2012.

The development of **SSR411298** an oral fatty acid amide hydrolase (FAAH) inhibitor as treatment of chronic pain in cancer patients has been initiated. The results of the on going Proof-of-Concept (POC) study are expected by the end of 2012 and should confirm the potential interest of the molecule in pain indication.

**Table of Contents****R&D expenditures for late stage development**

Expenditures on research and development amounted to 4,811 million in 2011, of which 4,101 million in the pharmaceutical segment, 564 million in Human Vaccines and 146 million in Animal Health. Research and development expenditures were the equivalent of about 14.4% of net sales in 2011, compared to about 14.1% in 2010 and 15.5% in 2009. The discontinuation of a number of projects contributed to the decrease in such expenditure in 2009 and 2010 and going forward the level of expenditure can be expected to continue to vary as a reflection of the number of products in late stage development among other factors. Preclinical research in the pharmaceutical segment amounted to 1,113 million in 2011, compared to 1,037 million in 2010 and 1,047 million in 2009. Of the remaining 2,988 million relating to clinical development in the pharmaceutical sector (2,848 million in 2010 and 3,043 million in 2009), the largest portion was generated by Phase III or post-marketing studies reflecting the cost of monitoring large scale clinical trials.

For each of our current late stage (Phase III) compounds in the Pharmaceutical segment, we set out below the date at which this compound entered into Phase III development, information concerning any compound patent in the principal markets for innovative pharmaceutical products (the United States, European Union and Japan) as well as comments regarding significant future milestones that are reasonably determinable at this date. Because the timing of such milestones typically depends on a number of factors outside of our control (such as the time to validate study protocols, recruit subjects, the speed with which endpoints are realized, as well as the substantial time taken by regulatory review) it is frequently not possible to provide such estimates, and any such estimates as are given should be understood to be indicative only. See also Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

Phase III (month/year)	Entry into Phase III <sup>1</sup>	Compound Patent Term <sup>2</sup>			Comments
		U.S.	E.U.	Japan	
Lyxumia <sup>®</sup> (lixisenatide) <sup>4</sup>	May 2008 <sup>3</sup>	2020	2020	2020	Dossier submitted in Europe in October 2011; to be submitted in the U.S. in 2012.
Zaltrap <sup>®</sup> (aflibercept)	July 2006	2020	2020	2020 <sup>4</sup>	2 <sup>nd</sup> line colorectal cancer, dossier submitted in Europe in November 2011 and in the U.S. in February 2012.
ombrabulin (AVE8062)	June 2008	2016	2016	2016	1st line prostate cancer Phase III (VENICE) results expected in the second quarter 2012 Sarcoma Phase III results expected in the third quarter 2012
iniparib (BSI-201)	June 2009	2013	2014	N/A	Phase III program on going in 1 <sup>st</sup> line squamous Non Small Cell Lung Cancer  Phase II program in 2 <sup>nd</sup> line ovarian cancer to be launched in 2012



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Phase III (month/year)	Entry into Phase III <sup>1</sup>	Compound Patent Term <sup>2</sup>			Comments
		U.S.	E.U.	Japan	
Visamerin <sup>®</sup> /Mulsevo <sup>®</sup> (semuloparin) <sup>4</sup>	May 2008	2024	2023	2023	Dossier submitted in Europe and U.S. in September 2011
otamixaban	April 2010	2016	2016	2016	Phase III results in Acute Coronary Syndrome (ACS) expected in the fourth quarter 2012
Aubagio (teriflunomide) <sup>4</sup>	September 2004	2014	expired	expired	In the monotherapy treatment of multiple sclerosis, dossier submitted in August 2011 in U.S. and in February 2012 in Europe
					Adjunct therapy treatment of multiple sclerosis, Phase III program on going
Clolar <sup>®</sup> / Evoltra <sup>®</sup>	Life Cycle Management	expired	expired	expired	Treatment of Clinically Isolated Syndrome, Phase III program on going. Phase III program on going in the 1 <sup>st</sup> line treatment of Acute Myeloid Leukemia
SAR302503 (TG101348)	January 2012	2026	2026 <sup>4</sup>	2026 <sup>4</sup>	Phase III program on going in the treatment of myelofibrosis
Lemtrada (alemtuzumab)	September 2007 (MS)	2015	2014	expired	Dossier to be submitted in Europe and U.S. for the treatment of Relapsing forms of Multiple Sclerosis during the 1 <sup>st</sup> semester of 2012
New formulation Insulin glargine	December 2011	2015 <sup>5</sup>	2014	2014	Phase III program on going
Kynamro (mipomersen) <sup>4</sup>	August 2007	2025	pending	pending	Dossier submitted in Europe in July 2011 in the treatment of homozygous familial hypercholesterolemia (HoFH) and severe heterozygous familial hypercholesterolemia (HeFH)
					Phase III program in severe HeFH on going for a U.S. submission

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Phase III (month/year)	Entry into Phase III <sup>1</sup>	Compound Patent Term <sup>2</sup>			Comments
		U.S.	E.U.	Japan	
eliglustat tartrate	September 2009	2022	pending	pending	Phase III program on going in the treatment of Gaucher Disease type 1 results expected the 1 <sup>st</sup> quarter of 2013
sarilumab	August 2011	2028	2027	2027	Phase III program in the treatment of Rheumatoid Arthritis on going

<sup>1</sup> First entry into Phase III in any indication.

<sup>2</sup> Subject to any future supplementary protection certificates and patent term extensions.

<sup>3</sup> Development of lixisenatide as stand alone entity. A program evaluating the benefit of a combination of lixisenatide / Lantus® is currently in Phase I.

<sup>4</sup> Application pending.

<sup>5</sup> Including a 6-month pediatric extension.

With respect to the compound patent information set out above, investors should bear the following additional factors in mind.

The listed compound patent expiration dates do not reflect possible extensions of up to five years available in the United States, the European Union, and Japan for pharmaceutical products. See Patents, Intellectual Property and Other Rights Patent Protection for a description of supplementary protection certificates and patent term extensions.

Depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product.

Regulatory exclusivity tied to the protection of clinical data is complementary to patent protection, and in many cases may provide more efficacious or longer lasting marketing exclusivity than a compound's patent estate. See Patents, Intellectual Property and Other Rights Regulatory Exclusivity for additional information. In the United States the data protection generally runs five years from first marketing approval of a new chemical entity extended to seven years for an orphan drug indication, 12 years from first marketing approval of a biological product (e.g., aflibercept). In the European Union and Japan the corresponding data protection periods are generally ten years and eight years, respectively.

**Vaccines Research and Development**

Our human vaccine research and development (R&D) remains focused on improving existing vaccines, as well as on the development of new prophylactic vaccines.

**Table of Contents***Portfolio*

The Sanofi Pasteur R&D portfolio includes 13 vaccines currently in advanced development as shown in the table below. The portfolio includes five vaccines/antibody products for novel targets and eight vaccines which are enhancements of existing vaccine products.

<b>Phase I</b>	<b>Phase IIa</b>	<b>Phase IIb</b>	<b>Phase III</b>	<b>Submitted</b>
<b><i>Streptococcus pneumoniae</i> *</b>	<b>Meningitis A,C,Y,W conj.</b>		<b>Quadracel®</b>	<b>Hexaxim</b>
Meningitis & pneumonia vaccine	2 <sup>nd</sup> generation  meningococcal conjugate infant vaccine		DTP <sup>(1)</sup> IPV vaccine 4-6 years U.S.	DTP-HepB-Polio-Hib vaccine <sup>(1)</sup>
<b>Tuberculosis *</b>			<b>Dengue *</b>	
Recombinant subunit vaccine	<b>Rabies VRVg</b>		Mild-to-severe dengue fever vaccine	
<b>Rotavirus (Shantha)</b>	Purified vero rabies vaccine		<b>Fluzone® QIV</b>	
Live attenuated tetravalent rotavirus oral vaccine	<b>ACAM C. diff *</b>		Quadrivalent inactivated influenza vaccine	
<b><i>Pseudomonas aeruginosa</i> *</b>	<i>Clostridium difficile</i> Toxoid vaccine		<b>Vaxigrip® QIV IM</b>	
Antibody fragment product			Quadrivalent inactivated influenza vaccine	
Prevention of ventilator-associated pneumonia			<b>DTP-HepB-Polio-Hib vaccine <sup>(1)</sup></b>	

<sup>(1)</sup> D=Diphtheria, T=Tetanus, Hib=Haemophilus influenzae b, HepB=Hepatitis B, P=Pertussis.

\* New targets

**Project highlights**

This section focuses on Phase I compounds and novel targets. Other vaccines in Phase II or III are described in the section Vaccine Products above.



## **Influenza**

To sustain our global leadership in the development of influenza vaccine, our R&D efforts are focused on innovative approaches for assessing new formulations and alternative delivery systems (see Vaccine Products ).

## **Pediatric Combination & Adolescent/Adult Boosters**

Several pediatric vaccines are under development. Tailored for specific markets, they are aimed at protecting against five or all six of the following diseases: diphtheria, tetanus, pertussis, poliomyelitis (polio), *Haemophilus influenzae* type b infections and hepatitis B (see Vaccine Products ).

## **Meningitis**

*Neisseria meningitidis* bacteria is a leading cause of meningitis in the United States, Europe and elsewhere, affecting infants and children as well as adolescents. The primary focus of several ongoing projects related to Menactra<sup>®</sup> is to decrease the age at which this vaccine can first be administered. (see Vaccine Products ).

## **Pneumococcal Vaccine**

*Streptococcus pneumoniae* bacteria is the leading etiological agent causing severe infections such as pneumonia, septicemia, meningitis and otitis media, and is responsible for over three million deaths per year worldwide, of which one million are children. Anti-microbial resistance in *Streptococcus pneumoniae* has complicated the treatment of pneumococcal disease and further emphasized the need for vaccination to prevent large-scale morbidity and mortality.

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Sanofi Pasteur is focused on the development of a multi-protein-based pneumococcal vaccine. This approach should result in a vaccine with superior serotype coverage as compared to current polysaccharide or conjugate based vaccines and should not induce nor be sensitive to serotype replacement. Results from the first Phase I clinical trial of a bi-component formulation demonstrated safety and immunogenicity. Results from a second Phase I clinical trial to evaluate a third antigen also demonstrated safety and immunogenicity (ability to induce an immune response). A third Phase I clinical trial of a tri-component formulation began in September 2011 in adults, adolescents, and infants in Bangladesh.

### **Rabies Vaccine**

**Rabies mAb Post Exposure Prophylaxis** This product consists of two rabies monoclonal antibodies (MABs) that will be used in association with the rabies vaccine for post-exposure prophylaxis. The last Phase II clinical trial in India was initiated in November 2011. In 2011, Sanofi Pasteur reviewed the rabies mAb project, developed in partnership with Crucell. Crucell, acquired by Johnson & Johnson, will take over full responsibility for the development of the product and Sanofi Pasteur will market it, when the vaccine is available.

### **New Vaccine Targets**

**Dengue** Dengue fever has increasing epidemiological importance due to global socio-climatic changes. It is a major medical and economic burden in the endemic areas of Asia-Pacific, Latin America and Africa. It is also one of the leading causes of fever among travelers. Multiple approaches have been tested to develop a vaccine covering the four viral serotypes of dengue fever in order to prevent this disease and its severe complications (hemorrhagic fever). Results of a Phase II clinical trial in adults in the United States demonstrated proof of concept of the lead quadrivalent vaccine candidate. Sanofi Pasteur's dengue vaccine research program includes ongoing clinical studies (adults and children) in several countries in endemic regions. The first Phase III study was initiated in October 2010 in Australia. This final stage of clinical development aims at demonstrating that production of the vaccine on an industrial scale will meet the consistency criteria required for market authorizations. The study in Australia is the first to use our dengue vaccine doses produced on an industrial scale. Two Phase III studies to evaluate efficacy (Latin America and Asia Pacific) began in June 2011. In February 2011, Sanofi Pasteur announced that it was partnering with the International Vaccine Institute (IVI) to support the recently launched Dengue Vaccine Initiative (DVI) in collaboration with the Sabin Vaccine Institute, the Johns Hopkins University, and the WHO to support development of vaccines to control dengue fever.

**Tuberculosis** Statens Serum Institute of Denmark (SSI) has granted Sanofi Pasteur a license to its technology with regard to the use of certain fusion proteins in the development of a tuberculosis vaccine. The license from SSI includes access to the Intercell IC31<sup>®</sup> adjuvant. The candidate vaccine is made up of recombinant protein units. Results from the 2008 Phase I trial found that the H4/IC31 candidate was safe when administered to healthy adults living in a region of high endemic tuberculosis. Rapid and poly-functional antigen-specific T cell responses were induced following a single dose of the investigational vaccine. A second Phase I trial was initiated in Switzerland in December 2010, with full enrollment completed in June 2011.

**HIV** A follow-up study to the Phase III clinical trial in Thailand provided new clues in 2011 about the types of immune responses that may have played a role in the protection seen in 2009 with our ALVAC-HIV vaccine. Last year, Sanofi Pasteur entered into a public-private partnership with Novartis Vaccines, the Bill & Melinda Gates Foundation, the U.S. National Institutes of Health (NIH), the HIV Vaccine Trial Network, and the Military HIV Research Program to substantiate and extend the vector prime/protein subunit boost regimen used in Thailand. Plans are being made to also study the regimen in the Republic of South Africa. This collaboration is expected to further the field of HIV vaccine development by sharing resources and by providing the manufacturing component of a partnership of funding agencies, research organizations, governments, and experts in the field of HIV vaccine development. Sanofi Pasteur is also looking at its NYVAC-HIV vaccine replicating vectors by participating in the Pox-T-cell consortium and the IPPOX Foundation in the Collaboration for AIDS Vaccine Discovery (CAVD).

**ACAM-Cdiff** *Clostridium difficile* is a major public health concern in North America and Europe. In hospitals, it is the leading cause of infectious diarrhea in adults, particularly the elderly. The epidemiology of *Clostridium difficile* associated disease (CDAD) has been increasing at an alarming rate since 2003, driven

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primarily by the emergence of a treatment-resistant, highly virulent strain CD027. There is currently no vaccine available and the only vaccine candidate currently in development is ACAM-Cdiff. ACAM-Cdiff is a toxoid-based vaccine. Toxoids have been used as the basis of a number of highly successful licensed vaccines. This vaccine candidate has successfully completed Phase I clinical trials with more than 200 participants in which safety and immunogenicity were evaluated. Sanofi Pasteur received a positive response from the United States, FDA's Center for Biologics Evaluation & Research (CBER) on the Fast Track Development Program submission in 2010. In November 2010, our *Clostridium difficile* vaccine started Phase II of clinical study in the U.S. This trial is focused on evaluating prevention of the first episode of *Clostridium difficile* infection (CDI) in at-risk individuals, which includes adults with imminent hospitalization or current or impending residence in a long-term care or rehabilitation facility. Results from the first stage of this study showed the vaccine was safe and immunogenic and provided important information for dose selection. The ongoing stage 2 of the study is evaluating the dosing schedule.

***Pseudomonas aeruginosa*** In February 2010, Sanofi Pasteur entered into an agreement with KaloBios Pharmaceuticals, a U.S.-based, privately held biotech company, for the development of a humanized antibody fragment to both treat and prevent *Pseudomonas aeruginosa* (*Pa*) infections. Most serious *Pa* infections occur in hospitalized and critically or chronically ill patients primarily affecting the respiratory system in susceptible individuals and are a serious clinical problem due to their resistance to antibiotics. The two primary target indications for the antibody are prevention of *Pa* associated pneumonia in mechanically ventilated patients in hospitals, and prevention of relapses and potential improvement of treatment outcomes in patients with an ongoing *Pa* infection. Under the terms of the agreement, Sanofi Pasteur acquired worldwide rights for all disease indications related to *Pa* infections except cystic fibrosis and bronchiectasis, which Sanofi Pasteur has the option to obtain at a later date. KaloBios has already completed Phase I clinical trials one in healthy volunteers and one in cystic fibrosis patients and a small proof of concept Phase II clinical trial in mechanically ventilated patients.

**Rotavirus** Rotavirus is the leading cause of severe, dehydrating diarrhea in children aged under five globally. Estimates suggest that rotavirus causes over 25 million outpatient visits, over 2 million hospitalizations and over 500,000 deaths per year. The burden of severe rotavirus illness and deaths falls heavily upon children in the poorer countries of the world, with more than 80% of rotavirus-related deaths estimated to occur in lower income countries of Asia, and in sub-Saharan Africa. Two vaccines (RotaTeq® and Rotarix®) are licensed worldwide, but production of local vaccines is necessary to achieve wide coverage. Shantha has a non-exclusive license of rotavirus strains from the U.S. NIH and is developing a live-attenuated human bovine (G1-G4) reassortant vaccine. The license excludes Europe, Canada, United States, China and Brazil. The project is currently in Phase I.

## **Patents, Intellectual Property and Other Rights**

### **Patent Protection**

We own a broad portfolio of patents, patent applications and patent licenses worldwide. These patents are of various types and may cover:

active ingredients;

pharmaceutical formulations;

product manufacturing processes;

intermediate chemical compounds;

therapeutic indications/methods of use;

delivery systems; and

enabling technologies, such as assays.

Patent protection for individual products typically extends for 20 years from the patent filing date in countries where we seek patent protection. A substantial part of the 20-year life span of a patent on a new chemical entity has generally already passed by the time the related product obtains marketing approval. As a

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result, the effective period of patent protection for an approved product's active ingredient is significantly shorter than 20 years. In some cases, the period of effective protection may be extended by procedures established to compensate significant regulatory delay in Europe (a Supplementary Protection Certificate or SPC), the United States (a Patent Term Extension or PTE) and Japan (also a PTE).

Additionally, the product may benefit from the protection of patents obtained during development or after the product's initial marketing approval. The protection a patent affords the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of December 2011, an EPO patent application may cover the 38 European Patent Convention member states, including all 27 member states of the European Union. The granted European Patent establishes corresponding national patents with uniform patent claims among the member states. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ by country. Additionally, a number of patents prosecuted through the EPO may pre-date the European Patent Convention accession of some current European Patent Convention member states, resulting in different treatment in those countries.

We monitor our competitors and vigorously seek to challenge patent infringement when such challenges would negatively impact our business objectives. See Item 8 - A. Consolidated Financial Statements and Other Financial Information Patents of this annual report.

The expiration or loss of an active ingredient patent may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product. See Item 3. Key Information D. Risk Factors Generic versions of some of our products may be approved for sale in one or more of their major markets; and We may lose market share to competing remedies or generic brands if they are perceived to be equivalent or superior products. In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or from other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. See Focus on Biologics below. Patent protection is also an important factor in our animal health business, but is of comparatively lesser importance to our Consumer Health Care and generics businesses, which rely principally on trademark protection.

## **Regulatory Exclusivity**

In some markets, including the European Union and the United States, many of our pharmaceutical products may also benefit from multi-year regulatory exclusivity periods, during which a generic competitor may not rely on our clinical trial and safety data in its drug application. Exclusivity is meant to encourage investment in research and development by providing innovators the exclusive use for a limited time of the innovation represented by a newly approved drug product. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

In the United States, the FDA will not grant final marketing approval to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (generally five years) that commences upon the first marketing authorization of the reference product. The FDA will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge one year before the end of this regulatory exclusivity period (see the descriptions of ANDAs in Product Overview Challenges to Patented Products below). In addition to the regulatory exclusivity granted to NCEs, significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity. Also, under certain limited conditions, it is possible to extend unexpired U.S. regulatory and patent-related exclusivities by a pediatric extension. See Pediatric Extension, below.

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Further, in the United States, a different regulatory exclusivity period applies to biological drugs. The Biologics Price Competition and Innovation Act of 2009 ( BPCIA ), was enacted on March 23, 2010 as part of the much larger health care reform legislation known as the Patient Protection and Affordable Care Act

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( PPACA ). The BPCIA introduced an approval pathway for biosimilar products. A biosimilar product is a biologic product that is highly similar to the reference (or innovator) product notwithstanding minor differences in clinically inactive components, and which has no clinically meaningful differences from the reference product in terms of the safety, purity, and potency of the product. The BPCIA provides that an application for a biosimilar product that relies on a reference product may not be submitted to the FDA until four years after the date on which the reference product was first licensed, and that the FDA may not approve a biosimilar application until twelve years after the date on which the reference product was first licensed.

In the European Union, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the 8+2+1 rule.

In Japan, the regulatory exclusivity period varies from four years (for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions) to six years (for new drugs containing a medicinal composition, or requiring a new route of administration) to eight years (for drugs containing a new chemical entity) to ten years (for orphan drugs or new drugs requiring pharmaco-epidemiological study).

## **Emerging Markets**

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP) has required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005, although it provides a limited number of developing countries an extension to 2016. Additionally, these same countries frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property rights poses difficulties in certain countries. Additionally, in recent years a number of countries facing health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business The globalization of the Group's business exposes us to increased risks.

## **Pediatric Extension**

In the United States and Europe, under certain conditions, it is possible to extend a product's regulatory exclusivities for an additional period of time by providing data regarding pediatric studies.

In the United States, the FDA may ask a company for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements (regardless of whether the data supports a pediatric indication) may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called pediatric exclusivity). Our main products which have received FDA grants of pediatric exclusivity at some point are Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Allegra<sup>®</sup>, Ambien<sup>®</sup>/Ambien<sup>®</sup> CR, Plavix<sup>®</sup> Taxotere<sup>®</sup>, and Actonel<sup>®</sup>.



In Europe, a regulation on pediatric medicines provides for pediatric research obligations with potential associated rewards including extension of patent protection (for patented medicinal products) and regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products).

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### **Orphan Drug Exclusivity**

Orphan drug exclusivity may be granted in the United States to drugs intended to treat rare diseases or conditions (affecting fewer than 200,000 patients in the U.S. or in some cases more than 200,000 with no expectation of recovering costs).

Obtaining orphan drug exclusivity is a two-step process. An applicant must first seek and obtain orphan drug designation from the FDA for its drug. If the FDA approves the drug for the designated indication, the drug will receive orphan drug exclusivity.

Orphan drug exclusivity runs from the time of approval and bars approval of another application (ANDA, 505(b)(2), New Drug Application (NDA) or Biologic License Application (BLA)) from a different sponsor for the same drug in the same indication for a seven-year period. Whether a subsequent application is for the same drug depends upon the chemical and clinical characteristics. The FDA may approve applications for the same drug for indications not protected by orphan exclusivity.

Orphan drug exclusivities also exist in the European Union and Japan.

### **Product Overview**

We summarize below the intellectual property coverage in our major markets of the marketed products described above at [Pharmaceutical Products - Main Pharmaceutical Products](#). Concerning animal health products, Merial's intellectual property coverage is described above (see [Animal Health: Merial](#)). In the discussion of patents below, we focus on active ingredient patents (compound patents) and any later filed improvement patents listed, as applicable, in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (the [Orange Book](#)) or on their foreign equivalents. These patents tend to be the most relevant in the event of an application by a competitor to produce a generic version of one of our products or the equivalent of these patents in other countries (see [Challenges to Patented Products](#) below). In some cases, products may also benefit from pending patent applications or from patents not eligible for Orange Book listing (*e.g.*, patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for regulatory delay, the extended dates are presented below. U.S. patent expirations presented below reflect U.S. Patent and Trademark Office dates, and therefore do not reflect six-month pediatric extensions to the FDA's Orange Book dates for the products concerned (Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Plavix<sup>®</sup>, and Actonel<sup>®</sup>).

We do not provide later filed improvement patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the European Union. Specific situations may vary by country, most notably with respect to older patents and to countries having only recently joined the European Union.

We additionally set out any regulatory exclusivity from which these products continue to benefit in the United States, European Union or Japan. Regulatory exclusivities presented below incorporate any pediatric extensions obtained. While EU regulatory exclusivity is intended to be applied throughout the European Union, in some cases member states have taken positions prejudicial to our exclusivity rights. See [Regulatory Exclusivity](#) above.

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*Lantus® (insulin glargine)*

<b>U.S.</b> Compound: August 2014, protection extended to February 2015 by Pediatric extension	<b>E.U.</b> Compound: November 2014 in most of Western Europe	<b>Japan</b> Compound: November 2014
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<p><b>U.S.</b> Compound: June 2018</p>	<p><i>Apidra® (insulin glulisine)</i> <b>E.U.</b> Compound: September 2019 in most of the EU</p>	<p><b>Japan</b> Compound: May 2022</p>
<p>Later filed improvement patent: ranging through January 2023</p>	<p>Later filed improvement patent: March 2022</p>	<p>Later filed improvement patent: July 2022</p>
	<p>Regulatory exclusivity: September 2014</p>	<p>Regulatory exclusivity: April 2017</p>
<p><b>U.S.</b> Compound: expired</p>	<p><i>Taxotere® (docetaxel)</i> <b>E.U.</b> Compound: expired in most of the EU</p>	<p><b>Japan</b> Compound: June 2012</p>
<p>Generics on the market</p>	<p>Generics on the market</p>	<p>Later filed improvement patents: coverage ranging through November 2013</p>
<p><b>U.S.</b> Compound: expired</p>	<p><i>Eloxatin® (oxaliplatin)<sup>1</sup></i> <b>E.U.</b> Compound: expired</p>	<p><b>Japan</b> N/A<sup>3</sup></p>
<p>Later filed improvement patents: coverage ranging through August 2016<sup>2</sup></p>	<p>Generics on the market</p>	
<p><sup>1</sup> We do not own most Eloxatin® patents but license them from Debiopharm for marketing.</p>	<p><sup>2</sup> Generics removed from the market by court order. Return anticipated in August 2012. See Item 8 - A. Consolidated Financial Statements and Other Financial Information Patents Eloxatin® (oxaliplatin) Patent Litigation .</p>	
<p><sup>3</sup> No rights to compound in Japan.</p>		
<p><b>U.S.</b> Compound: March 2016 (up to March 2021 if PTE is granted)</p>	<p><i>Jevtana® (cabazitaxel)</i> <b>E.U.</b> Compound: March 2016</p>	<p><b>Japan</b> Compound: March 2016 (patent term extension to be determined once product is approved in Japan)</p>
<p>Later filed improvement patents: coverage ranging through December 2025</p>	<p>Later filed improvement patents: coverage ranging through September 2024</p>	<p>Later filed improvement patents: coverage ranging through September 2024</p>
<p>Regulatory exclusivity: June 2015</p>	<p>Regulatory exclusivity: March 2021</p>	<p>Regulatory exclusivity to be determined upon approval of a product in Japan</p>
<p><b>U.S.</b> Compound: no compound patent coverage</p>	<p><i>Lovenox® (enoxaparin sodium)</i> <b>E.U.</b> Compound: expired</p>	<p><b>Japan</b> Compound: expired</p>

Generics on the market

Regulatory exclusivity: January  
2016

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<p><b>U.S.</b> Compound: November 2011</p> <p>Extended to May 2012, by Pediatric exclusivity</p>	<p><i>Plavix® (clopidogrel bisulfate)</i> <b>E.U.</b> Generics on the market</p>	<p><b>Japan</b> Compound: February 2013</p> <p>Regulatory exclusivity: January 2014</p>
<p><b>U.S.</b> Compound: September 2011</p> <p>Extended to March 2012 by Pediatric exclusivity</p>	<p><i>Aprovel® (irbesartan)</i> <b>E.U.</b> Compound: August 2012 in most of the EU; exceptions: February 2013 in Latvia and May 2013 in Lithuania. No compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe and expired in 2011 in the Czech Republic, Hungary, Romania and Slovakia</p>	<p><b>Japan</b> Compound: March 2016</p> <p>Later filed improvement patent: coverage ranging through June 2016 (June 2021 if PTE granted)</p>
<p>Later filed improvement patents: coverage ranging through December 2015 with Pediatric exclusivity</p>	<p>Later filed improvement patents: coverage ranging through June 2016</p>	<p>Later filed improvement patent: coverage ranging through June 2016 (June 2021 if PTE granted)</p>
<p><b>U.S.</b> N/A<sup>1</sup></p>	<p>Generics on the market in some EU countries</p> <p><i>Tritace® (ramipril)</i> <b>E.U.</b> Compound: expired</p> <p>Generics on the market</p>	<p>Regulatory exclusivity: April 2016</p> <p><b>Japan</b> Compound: expired</p>
<p><b>U.S.</b> Compound: July 2012 (July 2016 if PTE petition is granted)</p>	<p><i>Multaq® (dronedaron hydrochloride)</i> <b>E.U.</b> Compound: expired</p>	<p><b>Japan</b> Compound: expired</p>
<p>Later filed improvement patent: formulation (June 2018)</p>	<p>Later filed improvement patent: formulation June 2018 (June 2023 if SPC granted)</p>	
<p>Regulatory exclusivity: July 2014</p>	<p>Regulatory exclusivity: November 2019</p>	
<p><b>U.S.</b></p>	<p><i>Stilnox® (zolpidem tartrate)</i> <b>E.U.</b></p>	<p><b>Japan</b></p>

<sup>1</sup> No rights to compound in the U.S.

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Compound patent: expired

Compound patent: expired

Compound patent: expired  
Regulatory exclusivity: expired.

Generics on the market

Generics on the market

Later filed improvement patent:  
Ambien® CR formulation  
(December 2019); not  
commercialized.

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<p><b>U.S.</b> N/A<sup>2</sup></p>	<p><b>Copaxone® (glatiramer acetate)<sup>1</sup></b> <b>E.U.</b> Compound: May 2015</p>	<p><b>Japan</b> N/A<sup>2</sup></p>
<p><sup>1</sup> As of February 29, 2012 Sanofi no longer markets or sells Copaxone®. See Item 4 B. Business Overview Other Pharmaceutical Products Alliance with Teva . <sup>2</sup> No rights to compounds in the U.S. and Japan.</p>		
<p><b>U.S.</b> N/A<sup>3</sup></p>	<p><b>Depakine® (sodium valproate)</b> <b>E.U.</b> Compound: expired  Later filed improvement patent: Depakine® Chronosphere  formulation (October 2017)</p>	<p><b>Japan</b> Compound: expired  Later filed improvement patent: Depakine® Chronosphere  formulation (October 2017)</p>
<p><sup>3</sup> No rights to compounds in the U.S.</p>		
<p><b>U.S.</b> Compound: expired</p>	<p><b>Allegra® (fexofenadine hydrochloride)</b> <b>E.U.</b> Compound: expired</p>	<p><b>Japan<sup>4</sup></b> Compound: expired</p>
<p>Generics on the market</p>	<p>Generics on the market</p>	<p>Later filed improvement patents: coverage ranging through January 2016</p>
<p>Converted to Over-the-Counter</p>		
<p><sup>4</sup> In December 2011, the Japan patent office found two patents covering Allegra® to be invalid. This decision is under appeal by Sanofi (see Item 8 A. Consolidated Financial Statements and Other Financial Information Patents Allegra® Patent Litigation of this annual report for further information).</p>		
<p><b>U.S.</b> Compound: expired</p>	<p><b>Nasacort® (triamcinolone acetonide)<sup>5</sup></b> <b>E.U.</b> Compound: expired</p>	<p><b>Japan</b> Compound: expired</p>
<p>Later filed improvement patents: formulation and method of use July 2016</p>	<p>Later filed improvement patent: formulation July 2017</p>	
<p>Generics on the market</p>		
<p><sup>5</sup> A license was granted to Barr Laboratories, Inc. in settlement of patent litigation.</p>		
<p><b>U.S.</b> Compound: expired</p>	<p><b>Xatral® (alfuzosin hydrochloride)</b> <b>E.U.</b> Compound: expired</p>	<p><b>Japan</b> Compound: expired</p>



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Generics on the market

Generics on the market

Generics on the market

**U.S.**

Compound: December 2013,

Extended to June 2014 by Pediatric

extension

*Actonel® (risedronate sodium)<sup>6</sup>*

**E.U.**

Compound: expired

**Japan**

Expired

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*Actonel® (risedronate sodium)<sup>6</sup>*

Later filed improvement patents: coverage ranging through June 2018

Later filed improvement patents: coverage ranging through June 2018

<sup>6</sup> On October 30, 2009, Procter & Gamble Pharmaceuticals (P&G) sold its pharmaceutical business to Warner Chilcott (WCRX) which became the successor to P&G in rights and interests for the Actonel® alliance and now holds the NDA and the patents for this product in the United States. We commercialize Actonel® with WCRX. See Item 5 Financial Presentation of Alliances .

*Amaryl® (glimepiride)*

**U.S.**  
Compound: expired

**E.U.**  
Compound: expired

**Japan**  
Compound: expired

*Insuman® (human insulin)*

**U.S.**  
Compound: N/A

**E.U.**  
Compound: N/A

**Japan**  
Compound: N/A

*Fabrazyme® (agalsidase beta)*

**U.S.**  
Compound: N/A

**E.U.**  
Compound: N/A

**Japan**  
Compound: N/A

Later filed improvement patents: coverage ranging through September 2015

Later filed improvement patents: November 2013

Biologics Regulatory Exclusivity: April 2015

Orphan regulatory exclusivity: January 2014

*Cerezyme® (imiglucerase)*

**U.S.**  
Compound: August 2013

**E.U.**  
Compound: N/A

**Japan**  
Compound: N/A

Later filed improvement patents: coverage ranging through September 2019

*Lumizyme® / Myozyme® (alglucosidase alfa)*

**U.S.**  
Compound: August 2018

**E.U.**  
Compound: July 2021

**Japan**  
Compound: N/A

Later filed improvement patents: coverage ranging through February 2023

Later filed improvement patents: coverage ranging through February 2023

Orphan Drug Exclusivity: April 2013

Orphan Regulatory Exclusivity: March 2016

Orphan Regulatory Exclusivity: April 2017

Biologics Regulatory Exclusivity: April 2018

Biologics Regulatory Exclusivity: March 2016

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<b>U.S.</b> Compound: N/A	<b>Renage<sup>®</sup> (sevelamer hydrochloride)</b> <b>E.U.</b> Compound: N/A	<b>Japan</b> Compound: N/A
Later filed improvement patent: coverage ranging through August 2013 and September 2014	Later filed improvement patent: August 2014	Later filed improvement patent: August 2014
	SPC coverage to January 2015 in certain EU countries	PTE protection to December 2016
<b>U.S.</b> Compound: N/A	<b>Renvela<sup>®</sup> (sevelamer carbonate)</b> <b>E.U.</b> Compound: N/A	<b>Japan</b> Compound: N/A
Later filed improvement patent: coverage ranging through August 2013 and September 2014	Later filed improvement patent: August 2014	Later filed improvement patent: August 2014
New dosage form regulatory exclusivity: August 2012		
<b>U.S.</b> Compound: expired	<b>Synvisc<sup>®</sup> (hyaline G-F 20)</b> <b>E.U.</b> Compound: N/A	<b>Japan</b> Compound: N/A
Later filed improvement patent: March 2012		
<b>U.S.</b> Compound: expired	<b>Synvisc One<sup>®</sup> (hyaline G-F 20)</b> <b>E.U.</b> Compound: N/A	<b>Japan</b> Compound: N/A
Later filed improvement patent: January 2028		

Patents held or licensed by the Group do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the presence of unexpired patents, competitors have launched generic versions of Eloxatin<sup>®</sup> in Europe, Allegra<sup>®</sup> in the United States (prior to the product being switched to over-the-counter status) and Plavix<sup>®</sup> in Europe.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which the Group determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent, a salt or crystalline form not claimed by our composition of matter patent, or an indication not covered by our method of use patent. See Item 3. Key Information D. Risk Factors Risks Relating to Legal Matters We rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected.

As disclosed in Item 8 of this annual report, we are involved in significant litigation concerning the patent protection of a number of our products.

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### **Challenges to Patented Products**

In the United States, companies have filed Abbreviated New Drug Applications (ANDAs), containing challenges to patents related to a number of our products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties as the original approved product. ANDAs may not be filed with respect to drugs licensed as a biological. See [Focus on Biologics](#) below. An ANDA relies on the safety and other technical data of the original approved product, and does not generally require the generic manufacturer to conduct clinical trials (thus the name abbreviated new drug application), presenting a significant benefit in terms of time and cost. As a result of regulatory protection of our safety and other technical data, the ANDA may generally be filed only five years following the initial U.S. marketing authorization of the original product. See [Regulatory Exclusivity](#) above. This period can be reduced to four years if the ANDA includes a challenge to a patent listed in the FDA's Orange Book. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then the FDA is barred from granting final approval to an ANDA during the 30 months following the patent challenge (this bar is referred to in our industry as a 30-month stay), unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder.

Procedures comparable to the ANDA exist in other major markets.

In the European Union, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing approval by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched and in some jurisdictions, even prior to launch (once launch is imminent), the patent holder may seek an injunction against such marketing if it believes its patents are infringed. See Item 8 of this annual report.

The accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See [Focus on Biologics](#) and [Regulation](#) below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent - or *a fortiori* the corresponding foreign patent - against another competing product due to factors such as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See [Item 3. Key Information D. Risk Factors Risks Relating to Legal Matters](#). We rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected.

### **Trademarks**

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to identify our products and to protect the sustainability of our growth. Trademarks are particularly important to the commercial success of our CHC, generics and retail animal health business.

It is our policy to protect and register our trademarks with a strategy adapted to each product or service depending on their countries of commercialization: *i.e.*, on a worldwide basis for worldwide products or services, or on a regional or local basis for regional or local products or services.

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The process and degree of trademark protection vary country by country, as each country applies its own trademark laws and regulations. In most countries, trademark rights may only be obtained through formal trademark application and registration. In some countries, trademark protection can be based primarily on use. Registrations are granted for a fixed term (in most cases ten years) and are renewable indefinitely, except in some countries where maintenance of the trademarks is subject to their effective use.

When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration certificate. Additionally, in certain cases, we may enter into a coexistence agreement with a third-party that owns potentially conflicting rights in order to better protect and defend our trademarks.

Our trademarks are monitored and defended based on this policy and in order to prevent counterfeit, infringement and/ or unfair competition.

## **Production and Raw Materials**

For many years, we have chosen to integrate the manufacture of our products in order to have better control of quality and distribution. Our manufacturing process consists of three principal stages: the manufacture of active pharmaceutical ingredients, the transformation of these ingredients into products, and packaging.

We have a general policy of producing our main active ingredients and principal products at our own plants in order to minimize our dependence on external manufacturers and ensure the strict and precise control of the product throughout the production cycle. In some cases however, we rely on third parties for the manufacture and supply of some active ingredients and medical devices. We also have outsourced certain production elements, particularly as part of supply framework agreements entered into within the context of plant divestitures, or in order to adapt locally to market growth in emerging markets. In particular, we outsource a part of the production of the active ingredients used in Stilnox<sup>®</sup> and Xatral<sup>®</sup>, and certain pharmaceutical product formulations. Our main pharmaceutical subcontractors are Famar, Haupt, Patheon, Catalent and Sofarimex. These subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See section 3.D. Risk factors Risks Relating to Our Business .

We also depend on third parties for the manufacture of certain products. Under our partnership with BMS, a multi-vendor supply and safety stock have been put in place for Plavix<sup>®</sup> (clopidogrel bisulfate) and Aprovel<sup>®</sup> (irbesartan).

Our pharmaceutical production sites are divided into three categories:

global sites, which serve all the markets. Situated principally in Europe, these are plants dedicated to the manufacture of our active ingredients, injectables and a number of our principal products in solid form;

regional sites, which serve the markets at a continent level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), marking our strong industrial presence in the emerging markets;

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local sites, which wholly serve the domestic market.

Sanofi Pasteur produces vaccines at sites located in North America, France, China, Thailand, Argentina and India. Le Trait (France) and Anagni (Italy) pharmaceutical sites form part of Sanofi Pasteur's industrial operations and carry out aseptic filling and freeze-drying activities. A new antigen production unit in Mexico for seasonal and pandemic influenza vaccines is scheduled to commence commercial production in 2012, once the necessary production and marketing approvals have been obtained from the Mexican authorities.

In 2011, our industrial operations diversified into rare diseases with the acquisition of Genzyme and the integration of Merial, Sanofi's dedicated animal health division.

Genzyme's activities throughout the world cover all biomedicine development stages, from initial research to clinical trials, regulatory matters, manufacture and marketing.

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Merial markets pharmaceutical products (Frontline<sup>®</sup>, Heartgard<sup>®</sup>, Zactran<sup>®</sup>, Previcox<sup>®</sup>) and a broad range of vaccines for different animal species (dogs, cats, horses, ruminants, pigs and fowl). A number of pharmaceutical products are subcontracted (Heartgard<sup>®</sup>, Eprinex<sup>®</sup>) but almost all veterinary vaccines are manufactured at its own plants. Merial's industrial operations dedicated to animal health cover all activities, from the purchase of raw materials through to the delivery of the finished products, ensuring its customers' needs can be met through a reliable and flexible offer that meets quality expectations. There are sixteen production sites spread across nine countries.

All of our pharmaceutical and vaccine facilities are Good Manufacturing Practices (GMP) compliant with international guidelines. Our principal sites are approved by the U.S. Food & Drug Administration (FDA): this includes our pharmaceutical facilities in Ambarès, Tours, Le Trait, Maisons-Alfort and Compiègne in France, Dagenham and Holmes Chapel in the United Kingdom, Frankfurt in Germany, Veresegehaz in Hungary and Saint Louis in the United States, as well as our vaccine facilities in Marcy l'Etoile and Val de Reuil (our worldwide distribution site) in France, Swiftwater in the United States and Toronto in Canada. The Genzyme facilities in the United States (Allston, Framingham, Ridgefield, Cambridge) and in Europe (Geel, Lyon, Haverhill and Waterford) are all FDA approved. Our animal health facilities in Athens, Gainesville, Berlin and Raleigh in the United States are managed by the U.S. Department of Agriculture (USDA). Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and our strategic finished products. This is the case of Lovenox<sup>®</sup>, for example.

In February 2011, we had received an FDA warning letter concerning our Frankfurt facility following a routine FDA inspection in September 2010. The warning letter cited GMP compliance issues in certain manufacturing processes, without referring to specific products. While believing that the points raised in the letter did not compromise the quality of our marketed products, we acted on this warning and worked towards satisfying the recommendations through a compliance first improvement action plan. In October 2011, we notified the FDA of the end of this program. We expect the FDA inspection to take place during the second quarter of 2012.

On May 24, 2010, Genzyme entered into a consent decree with the FDA relating to the Allston facility following FDA inspections at the Allston facility that resulted in 483 observations and a warning letter raising CGMP deficiencies. A consent decree is a court order entered by agreement between a company and the government (in this case the FDA) that requires the company to take certain actions as set out in the decree. Under the terms of Genzyme's consent decree, Genzyme paid an upfront disgorgement of past profits of \$175.0 million. Conditioned upon Genzyme's compliance with the terms of the consent decree, Genzyme is permitted to continue manufacturing at the site during the remediation process.

The consent decree requires Genzyme to implement a plan to bring the Allston facility operations into compliance with applicable laws and regulations. The plan must address any deficiencies previously reported to Genzyme or identified as part of a comprehensive inspection that was completed by a third-party expert in February 2011. This third party expert has been retained by Genzyme and will monitor and oversee the implementation of the remediation workplan. The required comprehensive remediation workplan was submitted to the FDA in April 2011 and accepted by the FDA in January 2012. The workplan is expected to take approximately four more years to complete. The workplan includes a timetable of specified remediation compliance milestones. If the milestones are not met in accordance with the timetable, the FDA can require us to pay \$15,000 per day, per affected drug, until these compliance milestones are met. Upon satisfying all compliance requirements in accordance with the terms of the consent decree, Genzyme will be required to retain an auditor to monitor and oversee ongoing compliance at the Allston facility for an additional five years. To date, all requirements of the consent decree, including all requirements of the workplan, have been met by Genzyme.

Genzyme will be meeting with the FDA to propose modifications to the workplan as a result of planned changes in manufacturing operations regarding Cerezyme<sup>®</sup> and Fabrazyme<sup>®</sup> for the Allston Landing Facility.

The new Genzyme Framingham (U.S.) facility was approved by the FDA and the EMA in January 2012 for the production of Fabrazyme<sup>®</sup> (agalsidase beta).



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The Merial animal health facilities are regulated by different authorities depending on the product and the country (EPA, FDA, USDA, EU GMP, local authorities).

More details about our manufacturing sites are found below at [Property, Plant and Equipment](#) .

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**Table of Contents****Health, Safety and Environment (HSE)**

The manufacturing and research operations of Sanofi are subject to increasingly stringent health, safety and environmental (HSE) laws and regulations. These laws and regulations are complex and rapidly changing, and Sanofi invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year and totaled approximately 105 million in 2011.

The applicable environmental laws and regulations may require Sanofi to eradicate or reduce the effects of chemical substance usage and release at its various sites. The sites in question may belong to the Group, be currently operational, or they may have been owned or operational in the past. Under some of these laws and regulations, a current or previous owner or operator of a property may be held liable for the costs of removal or remediation of hazardous substances on, under or in its property, or transported from its property to third party sites, without regard to whether the owner or operator knew of, or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred, the discharge of those substances was authorized.

Moreover, as is the case for a number of companies involved in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some Group sites in the past, and may still occur or be discovered at others. In the Group's case, such sites are mainly located in the United States, Germany, France, Hungary, the Czech Republic, Slovakia, Brazil, Italy and the United Kingdom. As part of a program of environmental audits conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Group sites. In cooperation with national and local authorities, the Group regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planned in Rochester, Cincinnati, Mount-Pleasant, East Palo Alto, Ambler and Portland in the United States; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset, Romainville, Neuville, Vitry and Toulouse in France; Dagenham in the United Kingdom; Brindisi and Garesio in Italy; Ujpest in Hungary; Hlohovec in Slovakia; Prague in the Czech Republic; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi. Sanofi may also have potential liability for investigation and cleanup at several other sites.

Provisions have been established for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. For example, in 2007 the State of New Jersey initiated a claim against Bayer CropScience seeking compensation for damages caused to natural resources (NRD) at a former Rhône-Poulenc site in the United States, resulting in indemnification claims by Bayer CropScience against the Group under contractual environmental guarantees granted at the time of Bayer's acquisition of the CropScience business. Rehabilitation studies and an NRD assessment are underway in a similar project in Portland, Oregon. Potential environmental contingencies arising from certain business divestitures are described in Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report. In 2011, Sanofi spent 41 million on rehabilitating sites previously contaminated by soil or groundwater pollution. During the year ended December 31, 2011, a comprehensive review was carried out relating to the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately 763 million as at December 31, 2011; this figure includes the provisions related to Genzyme.

Due to changes in environmental regulations governing site remediation, the Group's provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques considered, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations of Aventis arising from its past involvement in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See Item 3.D. Risk Factors - Environmental Risks of Our Industrial Activities .

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To our knowledge, the Group is not currently subject to liabilities for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained. Regular HSE audits

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(24 in 2011) are carried out by the Group in order to assess compliance with our standards (which implies compliance with regulations) and to initiate corrective measures. Additionally 17 specialized audits covering contractors or biosafety were done by our teams. Moreover, 172 loss prevention technical visits were carried out in 2011.

Sanofi has implemented a worldwide master policy on health, safety and the environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, 78 rules (policies) have been drawn up in the key fields of HSE management, Good HSE Practices, safety in the workplace, process safety, industrial hygiene, health in the workplace and protection of the environment.

### ***Health***

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. The Group's COVALIS committee classifies all chemical and pharmaceutical products handled within the Group and establishes workplace exposure limits for each of them. The Group's TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout the Group. See Item 3. Key Information D. Risk Factors Environmental Risks of Our Industrial Activities Risks from the handling of hazardous materials could adversely affect our results of operations .

Appropriate industrial hygiene practices and programs are defined and implemented in each site. These practices consist essentially of containment measures for collective and individual protection against exposure in all workplaces where chemical substances or biological agents are handled. All personnel are monitored with an appropriate initial and routine medical program, focused on the potential occupational health risks linked to their duties.

In addition, a committee has been set up to prepare and support the implementation of the new European Union REACH regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. To fully comply with the new European regulation on the labeling of chemicals (Classification Labeling Packaging), the Group has registered the relevant hazardous chemical substances with the European Chemicals Agency (ECHA).

### ***Safety***

Sanofi has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, Sanofi invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary Sanofi employees as well as our sub-contractors.

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The French chemical manufacturing sites in Aramon, Neuville-sur-Saône, Sisteron and Vertolaye, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, the Zentiva site in Hlohovec, Slovakia, and the chemical production site in Budapest, Hungary, are listed Seveso II (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to heightened security inspections due to the toxic or flammable materials stored on the sites and used in the operating processes.

Risk assessments of processes and installations are drawn up according to standards and internal guidelines incorporating the best state-of-the-art benchmarks for the industry. These assessments are used to fulfill

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regulatory requirements and are regularly updated. Particular attention is paid to any risk-generating changes: process or installation changes, as well as changes in production scale and transfers between industrial or research units.

Our laboratories that specialize in process safety testing, which are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined to define scale-up process conditions while transferring from development stage to industrial scale. All these data ensure the relevance of the risk assessments.

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry.

## ***Environment***

The main objectives of our environmental policy are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of our activities. In order to optimize and improve our environmental performance, we have a strategy of continuous improvement practiced at all our sites through the annual implementation of HSE progress plans. In addition, 55 sites are currently ISO 14001 certified. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2011, seven of our European sites were included in the scope of the European CO<sub>2</sub> Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

Our recent efforts in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. In 2011, we reduced carbon dioxide emissions caused by our sales representation car fleet by 10% versus 2010, due to the policy of using energy efficient cars as well as a reduction in the number of cars. Since 2005, in terms of our activity level per unit produced, our direct and indirect carbon dioxide emissions have decreased by 9.5% and 15.6% respectively<sup>(1)</sup>.

An internal committee of experts called ECOVAL assesses the environmental impact of the pharmaceutical agents found in products marketed by Sanofi. It has developed an environmental risk assessment methodology and runs programs to collect the necessary data for such assessments. Additional ecotoxicity assessments are being performed on certain substances which predate current regulations, in order to obtain information that was not gathered when they were launched (as regulatory requirements were different at that time) and evaluate environmental risks resulting from their use by patients.

## **Markets**

A breakdown of revenues by business segment and by geographic region for 2009, 2010 and 2011 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information is based on sales data from IMS Health MIDAS, retail and hospital for full year 2011, in constant euros (unless otherwise indicated). For more information on market shares and ranking, see Presentation of Financial and Other Information at the beginning of this document.

Genzyme's sales are included from date of acquisition.

- (1) The CO<sub>2</sub> emissions variations per produced unit are calculated for each business and added proportionally to their respective contribution to the total direct and indirect CO<sub>2</sub> emissions. Each business defines a specific indicator of its activity (e.g., hours worked for vaccines, number of boxes produced for pharmaceuticals, etc.).

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### **Marketing and Distribution**

Sanofi has a commercial presence in approximately 100 countries, and our products are available in more than 170. Our main markets in terms of net sales are, respectively:

Emerging Markets (see definition in B. Business Overview Strategy, above) represent 30.3% of our net sales, the largest contribution to net sales of any region. We are the leading healthcare company in emerging markets. In 2011, sales in emerging markets grew by 10.1% at constant exchange rates. This performance was due to robust organic growth (10.4% excluding Genzyme and A/H1N1 vaccines sales). Brazil sales were up 16.9% (excluding Genzyme and A/H1N1 vaccines sales), China sales were up 38.5% (excluding Genzyme), and Russia sales were up 7.4% (excluding Genzyme). In 2011, Asia and Latin America continued to deliver strong double digit sales growth of 15.7% and 18.1% respectively (excluding Genzyme and A/H1N1 vaccines sales). Sales in Eastern Europe and Turkey were slightly down (-0.4% excluding Genzyme and A/H1N1 vaccines sales), which were particularly impacted by price cuts and generic competition for Taxotere® in Turkey.

The United States represent 29.8% of our net sales; we rank thirteenth with a market share of 3.1% (3.1% in 2010). Sales in the U.S. were up 6.8% at constant exchange rates in 2011 (down 5.7% excluding Genzyme and A/H1N1 vaccines sales) reflecting the impact of generics of LovenoX®, Taxotere®, Ambien® CR, Allegra® and Xyzal®; partially off-set by Lantus® growth, Eloxatin® return to market exclusivity and the launch of Allegra® OTC.

Western Europe represents 27.3% of our net sales; we are the leading pharmaceutical company in France where our market share is 9.9% (10.1% in 2010), and we rank fifth in Germany with a 4.6% market share (after Copaxone® transfer and without taking into account parallel trade). In 2011, sales in Western Europe were down 4.0% at constant exchange rate (down 10.5% excluding Genzyme and A/H1N1 vaccines sales) due to the impact of generic competition for Plavix® and Taxotere® as well as the impact of austerity measures.

Japan represents 8.6% of our net sales; our market share is 3.4% (3.1% in 2010). Full-year 2011 sales in Japan were up 20.2% at constant exchange rate, or up 12.0% excluding Genzyme and were supported by Plavix® (up 22.9%), Allegra® (up 22.2%) and Hib vaccine sales.

A breakdown of our sales by geographic market is presented in Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed care organizations and government institutions. With regard to rare disease, renal, and biosurgery products, we sell these products directly to physicians as well. With the exception of Consumer Health Care products, these drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription.

We use a selection of channels to disseminate information about and promote our products among healthcare professionals and patients, ensuring that the channels not only cover our latest therapeutic advances but also our mature products, as they provide the foundation for satisfying major therapeutic needs. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and we sometimes use new media channels (such as the internet) to market our products. National education and prevention campaigns can be used to improve patients' knowledge of conditions.



Our medical representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics. As of December 31, 2011, we had a global sales force of 32,874 representatives: 9,866 in Europe, 4,866 in the United States, and 18,142 in the rest of the world.

Although we market most of our products through our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographic areas. Our major alliances are detailed at [Pharmaceutical Products](#) [Main pharmaceutical products](#) above. See also [Item 3. Key Information](#) [D. Risk Factors](#) We rely on third parties for the marketing of some of our products.

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Our vaccines are sold and distributed through multiple channels, including physicians, pharmacies, hospitals and distributors in the private sector, and governmental entities and non-governmental organizations in the public and international donor markets, respectively.

Our animal health products are sold and distributed through various channels, depending on the countries legislation for veterinary products. Merial takes into account each country's specific characteristics and sells either to veterinaries, chemists, or via wholesalers. In case of epizootics, Merial delivers directly to governments.

## **Competition**

The pharmaceutical industry continues to experience significant changes in its competitive environment. Innovative drugs, a broad product range, and a presence in all geographical markets are key factors in maintaining a strong competitive position.

There are four types of competition in the prescription pharmaceutical market:

competition between pharmaceutical companies to research and develop new patented products or new therapeutic indications;

competition between different patented pharmaceutical products marketed for the same therapeutic indication;

competition between original and generic products or between original biological products and biosimilars, at the end of regulatory exclusivity or patent protection; and

competition between generic or biosimilar products.

We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies. See Note D.21. to our consolidated financial statements included at Item 18 of this annual report.

Our prescription drugs compete in all major markets against patented drugs from major pharmaceutical companies like; AstraZeneca in cardiovascular disease, hypertension and oncology; Bayer-Schering in thrombosis prevention; Boehringer-Ingelheim in atherothrombosis; Bristol-Myers Squibb in oncology; Lilly in diabetes and oncology; GlaxoSmithKline in oncology, allergies, diabetes and thrombosis; Merck in hypertension, osteoporosis, diabetes and benign prostatic hyperplasia; Novartis in hypertension and oncology; Novo Nordisk in diabetes; Pfizer in oncology, thrombosis and allergies; Shire plc in rare diseases and in renal; Fresenius Medical Care in renal and Roche in oncology and osteoporosis.

In our Vaccines business, we compete primarily with multinational players backed by large healthcare groups, including Merck (outside Europe), GlaxoSmithKline, Pfizer (Wyeth), Novartis and Johnson & Johnson (Crucell).

In selected market segments, Sanofi Pasteur competes with mid-size international players (such as CSL of Australia in the influenza market for the Southern Hemisphere). Sanofi Pasteur also competes with an increasing number of manufacturers, entrenched in densely populated and economically emerging regions, which are leveraging their cost/volume advantage and raising their level of technical capability and quality standards to compete on more sophisticated antigens in their domestic markets and also in international donor markets. Multinational players are increasingly seeking alliances with manufacturers from emerging economies to secure positions in their markets of origin.

In our Animal Health business, we compete primarily with international companies like Pfizer in both production and companion animals; with Merck and Boehringer Ingelheim in production animals; with Boehringer Ingelheim mainly in the vaccines segment; with Novartis and Bayer for pets and particularly for pets parasiticides; with Virbac, Ceva and Vetoquinol, French companies with global presence, for pharmaceuticals and vaccines except for Vetoquinol operating only in the pharmaceutical segment .

We also face competition from generic drugs that enter the market when our patent protection or regulatory exclusivity expires, or when we lose a patent infringement lawsuit (see Patents, Intellectual Property and

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Other Rights (above). Similarly, when a competing patented drug from another pharmaceutical company faces generic competition, these generic products can also affect the competitive environment of our own patented product. See Item 3. Key Information D. Risk factors Risks related to our business .

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products for which patents or regulatory exclusivity have expired.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date. Such launch may occur notwithstanding the fact that the owner of the original product may already have commenced patent infringement litigation against the generics manufacturer. Such launches are said to be at risk for the promoter of the generic product because it may be required to pay damages to the owner of the original product in the context of patent infringement litigation; however, these launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Drug manufacturers also face competition through parallel trading, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market are imported into that domestic market by parallel traders, who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet. This situation is of particular relevance to the European Union, where these practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

Finally, pharmaceutical companies face illegal competition from counterfeit drugs. The WHO estimates that counterfeit products account for 10% of the market worldwide, rising to more than 30% in some countries. However, in markets where powerful regulatory controls are in place, counterfeit drugs are estimated to represent less than 1% of market value.

The WHO also estimates that 50% of drugs sold on illegal websites have been found to be counterfeit.

A counterfeit medicine is deliberately and fraudulently mislabeled with respect to its identity and/or its source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging. Sanofi is committed to being part of any efforts made to overcome drug counterfeiting and has implemented the following actions:

Intensification of close collaboration with international organizations and with customs and police to reinforce regulatory frameworks and to investigate suspected counterfeiters; and

Development of technologies to make drugs more difficult to copy through packaging protection programs and to ensure no direct traceability.

## **Regulation**

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The pharmaceutical and health-related biotechnology sectors are highly regulated. National and supranational health authorities administer a vast array of legal and regulatory requirements that dictate pre-approval testing and quality standards to maximize the safety and efficacy of a new medical product. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing, as well as mandatory post-approval commitments that may include pediatric development.

The submission of an application to a regulatory authority does not guarantee that a license to market will be granted. Furthermore, each regulatory authority may impose its own requirements during the course of the product development and application review. It may refuse to grant approval and require additional data before granting approval, even though the same product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls, product withdrawals and penalties for violations of regulations based on data that are made available to them.

Product approval can vary from six months or less to several years from the date of application depending upon the country. Factors such as the quality of data submitted, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

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In recent years, efforts have been made by the ICH (International Conference on Harmonization) participants to harmonize product development and regulatory submission requirements. The ICH consists of the regulatory agencies of the three founding members (European Union, Japan, United States), plus Health Canada and Swissmedic as observers. An example of these efforts is the Common Technical Document (CTD), which can be used in different ICH regions for a product application review, with only local or regional adaptation. Electronic CTD is becoming the standard for worldwide product submission. Interestingly, emergent countries are starting to participate in ICH standardization discussions, and could be more involved in the near future.

International collaboration between regulatory authorities continues to develop with implementation of confidentiality arrangements between ICH regulatory authorities, and with non-ICH regulatory authorities. Examples include work-sharing on Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) inspections and regular interactions identified as clusters (i.e. pediatrics, oncology, advanced therapy medicinal products, vaccines, pharmacogenomics, orphans, biosimilars, blood products) between the United States and the European Union, as well as creating permanent representatives from the FDA and Japanese Pharmaceutical and Medical Devices Agency (PMDA) now based in London, and a corresponding permanent representative from EMA at the FDA.

The requirement of many countries, including Japan and several member states of the European Union, to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators meaningfully extend the time for market entry beyond the initial marketing approval. While marketing authorizations for new pharmaceutical products in the European Union have been substantially centralized with the EMA, pricing and reimbursement remain a matter of national competence.

**In the European Union**, there are three main procedures by which to apply for marketing authorization:

The centralized procedure is mandatory for certain types of medicinal products. When an application is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission which adopts the final decision and grants a EU marketing authorization. Such a marketing authorization is valid throughout the EU and the drug may be marketed within all European Union member states.

If a company is seeking a national marketing authorization in more than one member state, the mutual recognition or decentralized procedure is available to facilitate the granting of harmonized national authorizations across member states. Both the decentralized and the mutual recognition procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one member state.

National authorizations are still possible, but are only for products intended for commercialization in a single EU member state or for line extensions to existing national product licenses.

Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as an approved reference product in the European Union. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is bioequivalent to the originator product (i.e., works in the same way in the patient's body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product's dossier. Generic product applications can be filed and approved in the European Union only after the originator product eight year data exclusivity period has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period from the date of approval of the originator product has elapsed.

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Another relevant aspect in the EU regulatory framework is the sunset clause : a provision leading to the cessation of the validity of any marketing authorization which is not followed by marketing within three years or not remaining on the market for a consecutive three year period.

Post-authorization safety monitoring of pharmaceutical products is carefully regulated in Europe. The EU pharmaceutical legislation for medicinal products describes the respective obligations of the marketing authorization holder and of the regulatory authorities to set up a system for pharmacovigilance in order to collect, collate and evaluate information about suspected adverse reactions.

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It is possible for the regulatory authorities to withdraw products from the market for safety reasons. The responsibilities for pharmacovigilance rest with the regulatory authorities of all the EU member states in which the marketing authorizations are held. In accordance with applicable legislation, each EU member state has a pharmacovigilance system for the collection and evaluation of information relevant to the benefit to risk balance of medicinal products. The regulatory authority regularly monitors the safety profile of the products available on its territory and takes appropriate action where necessary and monitors the compliance of marketing authorisation holders with their obligations with respect to pharmacovigilance. All relevant information is shared between the regulatory authorities and the marketing authorization holder, in order to allow all parties involved in pharmacovigilance activities to assume their obligations and responsibilities.

In 2010 new legislation aimed at strengthening and rationalizing the EU Pharmacovigilance System was approved, which will be enforced in July 2012. Changes include a strengthened legal basis for regulators to require post-authorization safety and efficacy studies throughout the life cycle of the medicinal product. An additional scientific committee called the Pharmacovigilance Risk Assessment Committee, with a key role in pharmacovigilance assessments (scope: all marketed drugs in the EU), is being established at the level of the EMA. This committee, which includes a patient representative, can hold public hearings. As a result, the Periodic Safety Update Report work-sharing procedure, as well as the new Urgent Union procedure should improve the harmonization of regulatory outcomes of safety evaluation for nationally authorized products.

Implementation of this pharmacovigilance legislation will be a particular priority in light of the highly-publicized Mediator affair in France. Given AFSSAPS' stature as a leading regulatory agency, as well as the way the European regulatory network is organized, (with national agencies that are closely entwined with the EMA through their experts' membership of EMA's scientific committees and groups), it is possible the affair will have EU repercussions. Indeed member states may bring additional tighter national requirements. For example, the recently French law of December 29, 2011 that aims at reinforcing the oversight of safety of medical products allows the French regulator to ask for clinical trials to be conducted against both an active comparator and placebo for marketing authorisation purposes.

In addition the EU regulatory framework for medical devices will undergo an in-depth revision in 2012, that will aim to improve coordination, evaluation and certification of medical devices, as well as reinforcing efficient vigilance and post-market surveillance systems with greater harmonization of EU member states' market surveillance activities.

**In the United States**, applications for drug and biological approval are submitted to the FDA for review which has broad regulatory powers over all pharmaceutical products that are intended for U.S. sale and marketing. To commercialize a product in the U.S., a New Drug Application (NDA) under the Food, Drug and Cosmetic (FD&C) Act or Biological License Application (BLA) under the Public Health Service (PHS) Act is submitted to the FDA with data for filing and pre-market review. Specifically, the FDA must decide whether the product is safe and effective for its proposed use, if the benefits of the drug's use outweigh its risks, whether the drug's labeling is adequate, and if the manufacturing of the drug and the controls used for maintaining quality are adequate to preserve the drug's identity, strength, quality and purity. Based upon this review, the FDA can require post-approval commitments and requirements. Approval for a new indication of a previously approved product requires the submission of a supplemental NDA (sNDA) for a drug or supplemental BLA (sBLA) for a biological product.

The FD&C Act provides another abbreviated option for NDA approved products, called the 505(b)(2) pathway. This pre-market application may rely on the FDA finding that the reference product has been found to be safe and effective by the FDA based upon the innovator's preclinical and clinical data.

Sponsors wishing to market a generic drug can file an Abbreviated NDA (ANDA) under 505(j) of the FD&C Act. These applications are abbreviated because they are generally not required to include data to establish safety and effectiveness, but need only demonstrate that their product is bioequivalent (i.e., performs in humans in the same manner as the originator's product). Consequently, the length of time and cost required for development of generics can be considerably less than for the originator's drug. An application for a generic drug product does not currently require a user fee payment; however this will likely change under GDUFA (Generic Drug User Fee Act) which is expected to be



introduced as an Omnibus Bill in 2012. User fees for generic drug applications are

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necessary to help alleviate the backlog of applications at the Office of Generics Drugs (OGD). The current review time for an ANDA exceeds 30 months. The ANDA pathway in the United States can only be used for copies of drugs approved under the FD&C Act and not for BLA approved biological products under the PHS Act.

**In Japan**, regulatory authorities can require local development studies. They can also request bridging studies to verify that foreign clinical data are applicable to Japanese patients and require data to determine the appropriateness of the dosages for Japanese patients. These additional procedures have created a significant delay in the registration of some innovative products in Japan compared to the European Union and United States. In order to solve this drug-lag problem, the MHLW (Ministry of Health, Labour and Welfare) introduced the new NHI (National Health Insurance) pricing system on a trial basis. Reductions in NHI prices of new drugs every two years is compensated by a Premium for a maximum of 15 years. Premium are granted in exchange for the development of unproved drugs/off-label indications with high medical needs. Pharmaceutical manufacturers are required to conduct literatures-based submission within 6 months or start a clinical trial for registration within one year after the official request. Otherwise, NHI prices of all products of the manufacturer would be reduced dramatically. In addition, the regulatory authorities have begun to promote multinational studies.

For generic products, the data necessary for filing is similar to that which is required in EU and U.S. Pharmaceutical companies only need to submit quality data, and data demonstrating bioequivalence to the originator product, unless the drug is administered intravenously.

### **Focus on Biologics**

Products can be referred to as biologics when they are derived from plant or animal tissues, including blood products or products manufactured within living cells (e.g., antibodies). Most biologics are complex molecules or mixtures of molecules which are difficult to characterize and require physico-chemical-biological testing, and an understanding of and control over the manufacturing process.

The concept of generics is not scientifically appropriate for biologics due to their high level of complexity and therefore the concept of biosimilar products is more appropriate. A full comparison of the purity, safety and efficacy of the biosimilar product against the reference biological product should be undertaken, including assessment of physical/chemical, biological, non-clinical and clinical similarity.

In the European Union, a regulatory framework for developing and evaluating biosimilar products has been in place since November 2005. The CHMP has issued several product/disease specific guidelines for biosimilar products. In March 2009, the CHMP adopted a guideline on preclinical and clinical development of biosimilars of low molecular weight heparins (LMWH). Currently in Europe a potential product candidate claiming to be biologically similar to Lovenox® must show therapeutic equivalence in terms of efficacy and safety in at least one adequately powered, randomized, double-blind, parallel group clinical trial. However in 2011, the EMA initiated the revision of several of the existing biosimilar guidelines (general guidelines, as well as product-related guidelines for recombinant insulins and LMWH).

While the EMA has adopted so far a balanced approach for all biosimilars, which allows evaluation on a case-by-case, in accordance with relevant biosimilar guidelines, it seems that there is some willingness to simplify the pathway in very specific circumstances. For a very simple biological fully characterized on the quality level, a biosimilar could be authorized based on a bioequivalence study only combined with an extensive quality package. With respect to vaccines, the CHMP position is that, at present, it is unlikely that these products may be characterized at the molecular level, and that each vaccine product must be evaluated on a case-by-case basis.

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In Japan, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on CMC (Chemistry, Manufacturing and Control), preclinical and clinical data to be considered for the development of the new application category of biosimilars. Different from the CHMP guidelines, the main scope of the guideline includes recombinant proteins and polypeptides, but not polysaccharides such as LMWH.

In the United States, several complex protein-based drugs have been approved as NDAs under the Federal Food Drug and Cosmetic Act (FD&C Act). It is currently possible to submit an abbreviated application (ANDA) with respect to those particular products (e.g., Lovenox<sup>®</sup>, Lantus<sup>®</sup>). Since an ANDA is not required to contain

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clinical trial data other than from bioequivalence studies, the appropriateness of an ANDA with respect to these NDA approved biological products raises significant scientific issues for the FDA. Lovenox<sup>®</sup> (enoxaparin) was approved as a drug by the FDA on March 29, 1993 under Section 505(b)(1) of the FD&C Act and not as a biologic under Section 351 of the Public Health Service Act; therefore it was not possible to submit a biosimilar of the product. An abbreviated NDA (ANDA/generic) application was submitted to FDA August 2005 by Momenta/Sandoz under section 505(j) of the FD&C Act. This application was approved in July 2010; the generic product was approved as therapeutically equivalent to Lovenox<sup>®</sup>. The FDA approved a second enoxaparin ANDA on September 19, 2011. The sponsor, Amphastar, had submitted the application in 2003. A third ANDA from TEVA, also submitted in 2003, is still pending.

U.S. law now provides for a pathway for biosimilar versions of a reference product licensed as a biological under the PHS Act. Healthcare reform legislation entitled the Patient Protection and Affordable Care Act, was signed into law by the President on March 2010. Title VII, Subtitle A Biologics Price Competition and Innovation, allows for the creation of a regulatory approval pathway for biosimilars and a litigation procedure for patent infringement lawsuits brought against biosimilar applicants.

Under the new law, the definition of biological product in section 351(i) is revised to include proteins, except any chemically synthesized polypeptide. In addition, the law describes how a biosimilar product may be highly similar to the reference product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product.

This law also stated that approval of an application under section 351(k) may not be made effective until 12 years after the date on which the reference product was first licensed under section 351(a). The date on which the reference product was first licensed does not include the date of approval of: (1) a supplement for the biological product that is the reference product; (2) a subsequent application by the reference product sponsor or manufacturer for a change (other than a structural modification) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength for the previously licensed reference product; or (3) a subsequent application by the reference product sponsor or manufacturer for a modification to the structure of the reference product that does not result in a change in safety, purity, or potency.

Other provisions of this new U.S. law state that ten years after enactment, certain biological products approved under section 505 of the FD&C Act will be deemed licensed under section 351 of the PHS Act. Prior to that time, the current legal interpretation is that they cannot be reference products for applications submitted under section 351(k) of the PHS Act. The new law also describes how a biological product that is shown to meet the new interchangeability standards, may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.

On February 15, 2012, the FDA published for consultation three draft guidances for biosimilar development: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product, and Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009. The Agency has stated at publicly attended meetings that they are conducting resource-intensive pre-IND meetings with sponsors on a range of biosimilar products.

### **Focus on transparency and public access to documents**

Over the last two to three years the pharmaceutical industry is subject to growing pressure for greater transparency about clinical trials (conduct and results). Regulatory authorities are also being pushed for more openness and transparency to make more comprehensive the rationale and

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basis of regulatory decisions on medicinal products, for enhanced credibility of the regulatory process. This is a meaningful driver of the transparency initiatives undertaken in several countries.

Pharmaceutical manufacturers have committed to publishing protocols and results of clinical studies performed with their products in publicly accessible registries. In addition, both ICH and non-ICH countries often impose mandatory disclosure of clinical trials information.

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From a regulatory perspective, ambitious initiatives have been undertaken by the major regulatory authorities.

EU pharmaceutical legislation for medicinal products requires national regulatory authorities and the EMA to actively publish information concerning authorisation and supervision of medicinal products. The EMA has introduced a series of initiatives aimed at improving the transparency of its activities, such as improving the format of the European Public Assessment Report, web-published product approvals, withdrawals and rejections. In addition, there is an increased focus on comparative efficacy and effectiveness. With the new EU pharmacovigilance legislation, there will be an increased level of transparency especially with regard to communication of safety issues (e.g. public hearings, specific European web-portals with information on medicinal products). Finally, patients and consumers are increasingly involved in the work of the EMA's scientific committees.

The European regulators recently took a major step towards more openness and transparency by giving a considerably wider access to documents originated by pharmaceutical companies and submitted to the regulatory authorities for scientific evaluation, after a regulatory decision is taken. Whilst it is anticipated that these documents should be redacted before disclosure in order to protect information contained therein that cannot be disclosed (commercial confidential information or personal data), the identification of commercially confidential information (CCI) and protection of personal data (PPD) within the structure of the marketing-authorization dossier has been restricted according to the draft document released in June 2011 for public consultation by the EMA and the Head of Medicines Agencies (HMA). Therefore, the scope of the information accessible to the public is considerably widened (e.g., clinical study reports in a marketing authorization dossier, but also major parts of non-clinical test data).

In the highly competitive field of medicinal products, there is the need to reinforce the principle that non-innovators cannot obtain marketing authorization solely based on the originator's data released in the EU and while the data protection period runs.

In the U.S., the FDA has initiated a transparency initiative in response to President Obama's January 2009 Open Government Initiative. The objective of the initiative was to render the FDA much more transparent and open to the American public by providing the public with useful, user-friendly information about agency activities and decision-making.

The FDA Transparency Initiative has three phases: Phase I - Improving the understanding of FDA basics (completed); Phase II - Improving FDA's disclosure of information to the public (ongoing); and Phase III - Improving FDA's transparency to regulated industry (ongoing). Proposals to improve transparency and access to information were released for consultation for both Phase II (May 19, 2010) and Phase III (January 6, 2011). Some of the less controversial proposals have been implemented; others, such as proactive release of information that the Agency has in its possession, may require revisions to U.S. federal regulations.

## **Pricing & Reimbursement**

Rising overall healthcare costs are leading to efforts to curb drug expenditures in most markets in which Sanofi operates. Increasingly these efforts result in pricing and market access controls for pharmaceuticals. The nature and impact of these controls vary from country to country, but some common themes are reference pricing, systematic price reductions, formularies, volume limitations, patient co-pay requirements, and generic substitution. In addition, governments and third-party payers are increasingly demanding comparative / relative effectiveness data to support their decision making process. They are also increasing their utilization of emerging healthcare information technologies such as electronic prescribing and health records to enforce transparency and tight compliance with these regulations and controls. As a result, the environment in which pharmaceutical companies must operate in order to make their products available to patients and providers who need them continues to grow more complex each year.

Significant changes in the Pharmaceutical/Healthcare environment emerged since 2010:

In the United States, 2011 was marked by continued implementation of the health insurance and market reforms that are expected to lead to a large number of uninsured being covered by 2014, either through

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state aid or mandatory coverage, with a system of fines for non-compliance. These reforms are the subject of litigation. These reforms will also lead to the establishment of health insurance exchanges which is expected to expand health care coverage.

In Europe, emergency cost containment measures and reforms introduced since 2010 in several countries (including, Germany, Greece, Spain, Portugal, and Ireland) are being implemented. These will significantly affect the size of the pharmaceutical market. A number of Central Eastern European countries are also implementing cost containment measures (Hungary, Slovakia, Poland). In parallel, the full effect of the new German laws (end to the free-price-setting system) has only just begun to see negative dividends for industry. France has implemented, in 2011, numerous changes to pharmaceutical access. In addition, health economic assessment is now officially part of the price determination in countries such as France and Spain. Details of the UK value-based pricing of drugs scheme is still to be finalized and it is not clear how or if the emphasis of the Incremental Cost Effectiveness Ratio (ICER) used by the National Institute for Clinical Excellence (NICE) will be diminished.

In Asia, while the Chinese market continues to grow, the National Development and Reform Commission continues to bring controls on drug prices through severe price cuts. As with China, in India, there is a strong move towards a universal minimum health coverage, with the National Pharmaceutical Pricing Authority also pushing for price control of an essential drug list (EDL).

In Russia, healthcare provision guarantees were signed into law with as yet undefined treatment standards to control usage. However, the 2012 EDL has been established but prices have not been changed considerably.

In Japan, with the usual biennial price cuts (April 2012), the extension of price premiums for drug development and measures to encourage the access to new medications have been announced. In South Korea, after many announcements on pricing and reimbursement revisions the government is looking into premium measures for innovative products.

Regardless of the exact method, we believe that third-party payers will continue to act to curb the cost of pharmaceutical products. While the impact of these measures cannot be predicted with certainty, we are taking the necessary steps to defend the accessibility and price of our products in order to reflect the value of our innovative product offerings:

We actively engage with our key stakeholders on the value of our products to them. These stakeholders – including physicians, patient groups, pharmacists, government authorities and third-party payers – can have a significant impact on the market accessibility of our products.

We continue to add flexibility and adaptability to our operations so as to better prepare, diagnose, and address issues in individual markets.

Keeping in mind the importance of recognizing the value of our products and the high cost of research and development, we continue to analyze innovative pricing and access strategies that balance patient accessibility with appropriate rewards for innovation.

## **Insurance and Risk Coverage**

We are protected by four key insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our captive insurance company, Carraig Insurance Ltd (Carraig).

These four key programs cover Property & Business Interruption, General Liability, Stock and Transit, and Directors & Officers Liability.



Our captive insurance company, Carraig, participates in our coverage for various lines of insurance including, but not only, excess property, stock and transit and product liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly-owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover. It sets premiums for Group entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly verified and confirmed by independent actuaries.

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Our Property & Business Interruption program covers all Group entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between Group entities, enabling us to set deductibles and guarantees that are appropriate to the needs of local entities. It also incorporates a prevention program, including a comprehensive site visit program covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites. Specialist site visits are conducted every year to address specific needs, such as testing of sprinkler systems or emergency plans to deal with flooding risks.

The Stock and Transit program protects goods of all kind owned by the Group that are in transit nationally or internationally, whatever the means of transport, and all our inventories wherever they are located. Sharing risk between Group entities means that we can set deductibles at appropriate levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with our insurers, implementing best practices in this area at our distribution sites. This program, which is led by our captive insurance company, has substantial capacity, largely to deal with the growth in sea freight which can lead to a concentration of value in a single ship.

Our General Liability & Product Liability program has been renewed for all our subsidiaries worldwide wherever it was possible to do so, despite the increasing reluctance in the insurance and reinsurance market to cover product liability risks for large pharmaceutical groups. For several years, insurers have been reducing product liability cover because of the difficulty of insuring some products that have been subject to numerous claims. These products are excluded from the cover provided by insurers, and hence from the cover obtained by us on the insurance market. This applies to a few of our products, principally those described in Note D.22.a) to our consolidated financial statements included at Item 18 in this annual report. Because of these market conditions we have increased, year by year, the extent to which we self-insure.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at the country level, the greatest level of risk being retained by our captive insurance company. The level of risk self-insured by the Group including our captive reinsurance company enables us to retain control over the management and prevention of risk. Our negotiations with third-party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase, for the discrepancies in risk exposure between European countries and the United States, and for specific issues arising in certain jurisdictions. Coverage is adjusted every year in order to take into account the relative weight of new product liability risks such as those emerging from healthcare products which are not subject to market approval.

Our cover for risks that are not specific to the pharmaceutical industry (general liability) is designed to address the potential impacts of our operations.

In respect of all lines of business of Carraig, outstanding claims are covered by provisions for the estimated cost of settling all claims incurred up to, but not paid at the balance sheet date, whether reported or not, together with all related claims handling expenses. Where there is sufficient history from the company or from the market of claims made and settlements, an incurred but not reported (IBNR) actuarial technique is developed by management with the assistance of expert external actuaries to determine a reasonable estimate of the captive's exposure to unasserted claims for those risks. The actuaries perform an actuarial valuation of the IBNR loss and ALAE (allocated loss adjustment expense) liabilities of the Company as of year end. Two ultimate loss projections (based upon reported losses and paid losses respectively) using the Bornhuetter-Ferguson method are computed each year. Provisions are recorded on that basis.

The Directors & Officers Liability program protects all our legal entities and their directors and officers. Our captive insurance company is not involved in this program.

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These insurance programs are backed by best-in-class insurers and reinsurers and are designed in such a way that we can integrate most newly-acquired businesses on a continuous basis. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. This is now also the case for Genzyme and Merial which are integrated in the Group cover at each inception date. By centralizing our major programs, not only do we reduce costs, but we also provide world-class coverage for the entire Group.

**Table of Contents****C. Organizational Structure**

Sanofi is the holding company of a consolidated group of subsidiaries. The table below sets forth our significant subsidiaries and affiliates as of December 31, 2011. For a complete list of our main consolidated subsidiaries, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

<b>Significant Subsidiary or Affiliate</b>	<b>Country of Organization</b>	<b>Ownership and Voting Interest</b>
Aventis Inc.	United States	100%
Aventis Pharma S.A.	France	100%
Genzyme Corporation	United States	100%
Hoechst GmbH	Germany	100%
Merial Ltd	United Kingdom	100%
Merial S.A.S.	France	100%
Sanofi-Aventis Amérique du Nord S.A.S.	France	100%
Sanofi-Aventis Deutschland GmbH	Germany	100%
Sanofi-Aventis Europe S.A.S.	France	100%
Sanofi-Aventis France	France	100%
Sanofi-Aventis K.K.	Japan	100%
Sanofi-Aventis Participations S.A.S.	France	100%
Sanofi-Aventis U.S. LLC	United States	100%
Sanofi Pasteur Inc.	United States	100%
Sanofi-Synthelabo Inc.	United States	100%
Sanofi-Synthelabo UK Ltd	United Kingdom	100%
Sanofi Winthrop Industrie	France	100%

Sanofi and its subsidiaries form a group, organized around three activities: Pharmaceutical products, Human Vaccines and Animal Health products.

The patents and trademarks of the pharmaceutical activity are primarily owned by the Sanofi parent company, Aventis Pharma S.A. (France), Hoechst GmbH (Germany), Sanofi-Aventis Deutschland GmbH (Germany) and Genzyme Corporation (United States). The main patents and trademarks of the Human Vaccines and Animal Health activities are owned by Sanofi Pasteur S.A. and Merial Ltd, respectively.

Within the Group, the holding company oversees research and development activities by defining strategic priorities, coordinating work, and taking out industrial property rights under its own name and at its own expense. In order to fulfill this role, Sanofi subcontracts research and development to its specialized French and foreign subsidiaries, in many cases licensing its patents, manufacturing know-how and trademarks. In these cases, the licensee subsidiaries manufacture and distribute the Group's products, either directly or via local distribution entities.

In certain countries, Sanofi carries out part of its business operations through ventures with local partners. In addition, the Group has signed worldwide alliances by which two of its products (Plavix<sup>®</sup> and Aprovel<sup>®</sup>) are marketed through an alliance with BMS and Actonel<sup>®</sup> is marketed through an alliance with Warner Chilcott. See [Pharmaceutical Products](#) [Main Pharmaceutical Products](#) above.

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For most Group subsidiaries, Sanofi provides financing and centrally manages their cash surpluses. Under the alliance arrangement with BMS, cash surpluses and cash needs arising within alliance entities give rise to symmetrical monthly transfers between the two groups. The holding company also operates a centralized foreign exchange risk management system, which enters into positions to manage the operational risks of its main subsidiaries.

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### ***D. Property, Plant and Equipment***

Our headquarters are located in Paris, France. See Office Space below.

We operate our business through offices and research, production and logistics facilities in approximately 100 countries. All our support functions operate out of our office premises. A breakdown of these sites by use and by ownership/leasehold status is provided below. Breakdowns are based on surface area. All surface area figures are unaudited.

#### **Breakdown of sites by use\***

Industrial	59%
Research	18%
Offices	13%
Logistics	6%
Other	4%

\* The Group's Human Vaccines and Animal Health businesses include offices and research, production and warehouse facilities. They are allocated between the four uses for premises shown at the top of the table above.

#### **Breakdown of the Group's sites between owned and leased**

Leased	32%
Owned	68%

We own most of our research and development and production facilities, either freehold or under finance leases with a purchase option exercisable at expiration.

#### **Research and Development Sites: Pharmaceuticals segment**

Research and Development activities are housed at 21 sites:

seven operational sites in France, in Vitry/Alfortville, Montpellier, Chilly-Longjumeau, Toulouse, Strasbourg and Lyon;

outside France, six sites are located in other European countries (Germany, UK, Holland and Italy), the largest being in Frankfurt, Germany;

seven sites in the United States, the largest being in Cambridge and Framingham;

one site in China, a Clinical Research Unit in Beijing.

### **Sanofi's Industrial Sites**

The Group has 116 production sites for pharmaceuticals (including rare diseases), vaccines and animal health located in 40 countries.

Sanofi believes its production plants and research centers are in compliance with all regulatory requirements, are properly maintained and are generally suitable for future needs. Nonetheless, the Group regularly inspects and evaluates its production facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about the Group's property, plant and equipment, see Note D.3 to the consolidated financial statements.

### **Industrial Sites: Pharmaceuticals Segment**

Production of chemical and pharmaceutical products is the responsibility of our Industrial Affairs function, which is also in charge of most of our logistics facilities (distribution and storage centers).

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The sites where the major Sanofi drugs, active ingredients, specialties and medical devices are manufactured are:

France: Ambarès (Aprovel<sup>®</sup>, Depakine<sup>®</sup>, Multaq<sup>®</sup>), Le Trait (Lovenox<sup>®</sup>), Maisons-Alfort (Lovenox<sup>®</sup>), Neuville (dronedarone), Quetigny (Stilnox<sup>®</sup>, Plavix<sup>®</sup>), Sisteron (clopidogrel bisulfate, dronedarone, zolpidem tartrate), Tours (Stilnox<sup>®</sup>, Aprovel<sup>®</sup>, Xatral<sup>®</sup>), Vitry-sur Seine / Alfortville (docetaxel);

Germany: Frankfurt (insulins, ramipril, Lantus<sup>®</sup>, Tritace<sup>®</sup>, pens, Apidra<sup>®</sup>);

Italy: Scoppito (Tritace<sup>®</sup>, Amaryl<sup>®</sup>) and Anagni (Depakine<sup>®</sup>, Fasturtec<sup>®</sup> and Rifa antibiotic family);

United Kingdom: Dagenham (Taxotere<sup>®</sup>, Elaxotine<sup>®</sup>), specialties currently being transferred to Frankfurt, Fawdon (Plavix<sup>®</sup>, Aprovel<sup>®</sup>); Holmes Chapel (Nasacort<sup>®</sup>);

Hungary: Ujpest (irbesartan), Csanyikvölgy (Lovenox<sup>®</sup>);

Japan: Kawagoe (Plavix<sup>®</sup>);

United States: Kansas City (Allegra<sup>®</sup>), speciality currently being transferred to Tours and Compiègne, and Chattanooga (Consumer Health Care products).

In the field of rare diseases, Genzyme became a Sanofi subsidiary in April 2011. This acquisition expands the Group's presence in biotechnologies, especially rare diseases. Genzyme manages 11 production sites and collaborates with over 20 subcontractors to manufacture 22 commercial products over an entire range of technological platforms

Genzyme sites are as follows:

United States, Massachusetts: Allston (Cerezyme<sup>®</sup>), Framingham (Fabrazyme<sup>®</sup>, Myozyme<sup>®</sup>, Thyrogen<sup>®</sup>, Septrafilm<sup>®</sup>, Hyaluronic Acid); Cambridge (Carticel<sup>®</sup>, Epicel<sup>®</sup>, MACI<sup>®</sup> (Matrix-induced Autologous Chondrocyte Implantation)) ;

United States, New Jersey: Ridgefield (Synvisc<sup>®</sup>, Hectorol<sup>®</sup>, Mozobil<sup>®</sup>, Jonexa<sup>®</sup>, Prevelle<sup>®</sup>);

Ireland: Waterford (Myozyme<sup>®</sup>, Lumizyme<sup>®</sup>, Cholestagel<sup>®</sup>, Thymoglobuline<sup>®</sup>, Renagel<sup>®</sup>, Renvela<sup>®</sup>, Cerezyme<sup>®</sup>);

United Kingdom, Suffolk: Haverhill (sevelamer hydrochloride API (Renagel<sup>®</sup>), sevelamer carbonate API (Renvela<sup>®</sup>), Cerezyme<sup>®</sup>, Fabrazyme<sup>®</sup>, Thyrogen<sup>®</sup>, Myozyme<sup>®</sup>, etc).

Belgium: Geel (alglucosidase alfa: Myozyme<sup>®</sup>/Lumizyme<sup>®</sup>);



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France: Lyon (Thymoglobuline<sup>®</sup>, Celsior<sup>®</sup> (Immunosuppression in transplantation: preventing and treating graft rejection));

Denmark: Copenhagen (MACI<sup>®</sup>);

Australia: Perth (MACI<sup>®</sup>);

### **Sanofi Pasteur Industrial Sites**

The headquarters of the Group's Vaccines division, Sanofi Pasteur, are located in Lyon, France. Sanofi Pasteur's production and/or Research and Development sites are located in Swiftwater, Cambridge, Rockville Canton and Orlando, United States, Toronto, Canada, Marcy l'Etoile, Neuville and Val de Reuil, France, Shenzhen, China, Pilar, Argentina, Chachoengsao, Thailand, Hyderabad, India, and Ocoyoacac, Mexico.

In May 2009, Sanofi launched the construction of a new vaccine manufacturing center in Neuville-sur-Saône, France. This 300 million site investment is the largest ever made by Sanofi. The objective is to progressively transition the existing chemical activity to vaccine production beginning in 2013.

In 2010, Sanofi Pasteur acquired VaxDesign, a U.S. company located in Orlando, Florida. VaxDesign's Modular IMMune In-vitro Construct (MIMIC<sup>®</sup>) System is designed to capture genetic and environmental diversity and predict human immune responses. The MIMIC<sup>®</sup> platform is expected to accelerate vaccine development, reduced time to market and increased probability of success rates in pre-clinical and clinical stages.

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Sanofi Pasteur owns its Research and Development and production sites, either freehold or under finance leases with a purchase option exercisable at expiration.

### **Animal Health Industrial Sites (Merial)**

Since the announcement of Merck and Sanofi in March 2011 that they will maintain separate activities in the field of animal health, Merial has become a dedicated Sanofi division. Merial has 16 industrial sites, distributed throughout nine countries; nine research and development sites and numerous administrative offices with its principal headquarters located at Lyon, France.

Merial industrial sites are as follows:

Brazil: Paulinia (ivermectin-based pharmaceutical products and vaccines to prevent foot-and-mouth disease and rabies);

China: Nanchang (live avian vaccines) and Nanjing (inactivated avian vaccines);

France: Toulouse (Frontline<sup>®</sup> and clostridial vaccines), St-Priest LPA (vaccines), Lyon Gerland, Saint-Herblon (Coophavet), Lentilly (packaging);

Italy: Noventa (inactivated avian vaccines);

Netherlands: Lelystad (antigen and vaccine against foot-and-mouth disease);

Uruguay: Montevideo (primarily anti-clostridium antigens);

United Kingdom: Pirbright (antigens and vaccines against foot-and-mouth disease);

United States: Berlin, Maryland, Gainesville, Georgia, and Raleigh, North Carolina, three Merial sites dedicated to Merial's avian business; and Athens, Georgia dedicated to viral and bacterial vaccines for mammals;

New Zealand: Auckland, Ankara (pharmaceutical products mainly for ruminants).

### **Acquisitions, Capital Expenditures and Divestitures**

The carrying amount of our property, plant and equipment at December 31, 2011 was 10,750 million. In 2011, we invested 1,440 million (see Note D.3. to the consolidated financial statements) in increasing capacity and improving productivity at our various production and R&D sites.

The Group's principal capital expenditures and divestments for, 2009, 2010, and 2011 are set out in this annual report at Item 5. Operating and Financial Review and Prospects Divestments , Acquisitions and Liquidity and Capital Resources and in Note D.1., Note D.2., Note D.3. and Note D.4. to our consolidated financial statements included at Item 18 of this annual report.

Our principal investments in progress are described below:

### **Pharmaceuticals Segment**

In Europe, we continued to optimize our industrial facilities, in particular by investing in two new Lantus® production lines at the Frankfurt site and acquiring the Diabel manufacturing site from Pfizer to strengthen our insulin production capacity. We invested in the Brindisi (Italy) site to expand its production of spiramycin, the active ingredient of the antibiotic Rovamycin®. In the United States, we are investing ahead of the launch of epiCard, a gas powered single dose, single use auto-injector with audible user instructions for the injection of epinephrine, indicated for the emergency treatment of severe allergic reactions.

We have also begun the Biolaunch project, designed to convert our chemical facilities to biotechnologies, with a project to create a monoclonal antibody production facility at our Vitry-sur-Seine site in France from 2012, plus investments in the creation of a new innovative biosynthetic process at the Saint-Aubin-Lès-Elbeuf and Vertolaye industrial sites, in order to improve our corticosteroid production competitiveness at a global level.

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In Emerging Markets, we currently rely on industrial sites dedicated to serving regional markets, a situation reinforced by our 2009 acquisitions (Zentiva in Eastern Europe and Medley in Brazil). In China, the project to extend our current manufacturing facility located at the Beijing Economic and Technological Development Area enables us to install assembly and packaging lines for SoloSTAR<sup>®</sup>, the pre-filled injection pen used to administer Lantus<sup>®</sup> (insulin glargine). In Hangzhou (China), we are building a new manufacturing site to replace the current manufacturing facility in downtown Hangzhou. The new site is scheduled to be completed in 2012. In Russia, the Orel insulin factory, acquired following the deal with Bioton Vostok, is a key element of our strategy to improve and accelerate our access to the fast-growing Russian market. In the Middle East, Sanofi entered into an agreement with the King Abdullah Economic City to build a manufacturing facility for solid-dose form pharmaceuticals in Saudi Arabia. In Latin America, where Sanofi already has a broad industrial platform, the Group is building a plant in Brazilia to be dedicated to hormonal products.

Genzyme's industrial investments include the expansion of Myozyme<sup>®</sup> production capacity in Geel (Belgium), Fabrazyme<sup>®</sup> in Framingham (United States), Thymoglobulin<sup>®</sup> in Lyon (France) and for filling operations in Waterford (Ireland). Also, in the United States, a new laboratory and office spaces have been built in Framingham and the distribution center in Northborough has been expanded.

### **Vaccines Segment (Sanofi Pasteur)**

Our Vaccines business has invested significantly in recent years, with the construction of a state-of-the-art research facility in Toronto (Canada); the creation of a new vaccines campus in Neuville (France); the construction of bulk and filling facilities in Val de Reuil (France) and a bacteriological bulk facility in Marcy l'Étoile (France); the creation of two new influenza vaccine facilities in Shenzhen (China) and Ocoyoacac (Mexico); and the completion of bulk and filling facilities in Swiftwater (United States), mainly dedicated to influenza and meningitis vaccines.

### **Animal Health Segment (Merial)**

A significant proportion of the investment in Europe over the last several years has been allocated to transferring Lyon Gerland's vaccine production operations to the new Saint Priest site. In Toulouse, Merial adapted its production capacity to the arrival of new products. Merial invested in a packaging line for Certifect<sup>®</sup> production (managed according to the Good Manufacturing Practices applicable in the European Union, and approved by the Environmental Protection Agency in the United States) and an injectible facility for Zactran<sup>®</sup> production. In 2009, Merial acquired a site to produce vaccines against foot-and-mouth disease in Lelystad, Netherlands, which thereby granted Merial two foot-and-mouth vaccine production licenses of the three in existence in Europe.

In the United States, Merial has invested significantly in Athens, Georgia in a pharmaceutical form unit in an effort to increase its capacity to meet the growing number of products.

In Emerging Markets, Merial invested in China to transfer an existing site to a new production site located in Nanchang's high-tech development zone, in order to support future growth of avian and other species vaccines. In addition, Merial invested in a R&D laboratory in Shanghai in order to facilitate local vaccine development in China.

As of December 31, 2011, our firm orders related to future capital expenditure amounted to 292 million. They were mainly related to the following industrial sites: Frankfurt (Germany) and Elbeuf (France) for the Pharmaceuticals segment, Swiftwater (United States) and Neuville (France) for the Vaccines segment, and the La Boétie site (the Group's corporate headquarters in France).

In the medium term and on a constant structure basis, we expect our yearly average capital expenditure to be in the range of 1.7 billion. We believe that our existing cash resources and unused credit facilities will be sufficient to finance these investments.

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### **Office Space**

As part of the rationalization of our office sites in the Paris region of France, we have since mid-2009 been reviewing our medium-term office space master plan for the Greater Paris area.

This review is expected to result in all our Group support functions and operating divisions being housed on a smaller number of sites (five in 2012, when phase 1 is implemented). All of these sites will meet environmental certification standards, and offer cost-effective space solutions.

Closing of the property located in Gentilly, Val de Bièvre marked the 2011 step in this Master Plan.

Preparing our new global corporate headquarters in first quarter 2012 on the Rue La Boétie, in the 8th *arrondissement* of Paris, at the heart of the city's business district will bring all our Group support functions together within a single site, symbolizing the transformation of the Group.

Finally, our former corporate headquarters at 174 avenue de France in the 13th *arrondissement* of Paris will be closed in 2012, along with the adjacent site at 182 avenue de France.

The second phase of the Greater Paris office space master plan is currently under consideration, the aim being to reduce the overall area in use and the overall cost of operation.

A second Master Plan was initiated in late 2011 to outline the Group's medium-term office space needs for the greater Lyon area.

A project was launched to integrate office sites from the property portfolio of Genzyme and Merial, and represents a presence in 50 countries and 540,000 m<sup>2</sup>.

### **Item 4A. Unresolved Staff Comments**

N/A

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### **Item 5. Operating and Financial Review and Prospects**

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report at Item 18.

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2011.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See **Cautionary Statement Regarding Forward-Looking Statements** at the beginning of this document.

#### **2011 Overview**

In 2011, the Group, which changed its name to Sanofi following the May 2011 General Meeting of Shareholders, continued to implement its transforming and sustainable growth strategy through the year. Sanofi acquired Genzyme Corporation (Genzyme), a leading American biotechnology company specializing in rare diseases with operations in the areas of renal diseases, endocrinology, oncology, biosurgery, and multiple sclerosis. Despite competition from generics and their impact on the sales of some of our flagship products, as well as the absence of sales of pandemic Influenza A/H1N1 vaccines in 2011, our continuing efforts to establish growth platforms have helped the Group to improve its position in Emerging Markets, Diabetes, Vaccines, Consumer Health Care, and Animal Health. Sanofi has shown resilience in terms of net sales and profitability.

The Group's net sales for the year totaled 33,389 million, up 3.2% compared to 2010 (5.3% at constant exchange rates (see definition at **Presentation of Net Sales** below), buoyed by the solid performance of its growth platforms, Emerging Markets, Diabetes, Vaccines, Consumer Health Care, and Animal Health, as well as the consolidation of Genzyme (2,395 million in net sales from early April 2011), and this is despite significant competition from generics, which based on 2010 sales at constant exchange rates represented a 2.2 billion loss in net sales (see **Impacts from generic competition** below). In terms of organic growth developments, 2011 was especially marked by the launch of the cancer drug Jevtana® in the European Union, the approval of Allegra® for over-the-counter use in the United States, FDA approval of the influenza vaccine Fluzone® ID in the United States, and launch of Certifect® for animal health in the United States.

By continuing to adapt its resources, the Group has managed to reduce its R&D costs and its selling and general expenses by 2.4% and 2.6%, respectively (at constant exchange rates, excluding Genzyme). Business net income totaled 8,795 million, down 4.6% compared to 2010 on a reported basis, caused by the competition from generics and the absence of pandemic influenza A/H1N1 vaccine sales. Business earnings per share was 6.65, down 5.8% compared with 2010. Business net income and business earnings per share are non-GAAP financial measures which our management uses to monitor our operational performance, and which are defined at **Business Net Income** below.

Net income attributable to equity holders of Sanofi totaled 5,693 million, 4.1% higher than in 2010. Basic earnings per share for 2011 were 4.31, 2.9% higher than in 2010; diluted earnings per share for 2011 were 4.29 (2.6% higher).

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Sanofi continued to pursue its strategy of targeted acquisitions and R&D partnerships. The acquisition of Genzyme in April 2011 has been described above. In Consumer Health Care, the Group successfully completed its acquisition of BMP Sunstone in China. In Animal Health, Merial became Sanofi's dedicated animal health division following the joint statement issued by Merck and Sanofi in March 2011 announcing the end of their agreement to create a new animal health joint venture by combining their respective animal health activities. In addition, partnership and licensing agreements have enabled the Group to expand and to further develop its existing areas of research.

In September 2011, the Group announced new objectives for the 2012-2015 period based on three initiatives: improvement of growth platforms, maintenance of tight cost-control, and advances in transforming R&D. While we remain focused on these objectives, we expect erosion from generic competition to continue, with a negative impact on net income in 2012 (see Impacts from generic competition below).



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Our operations generate significant cash flow. We recorded 9,319 million of net cash provided by operating activities in 2011 compared to 9,859 million in 2010. During the course of 2011, we paid out 1.4 billion in dividends and contracted new debt of \$18.0 billion to finance the Genzyme acquisition. With respect to our financial position, we ended 2011 with our debt, net of cash and cash equivalents (meaning the sum of short-term and long-term debt plus related interest rate and currency derivatives, minus cash and cash equivalents) at 10,859 million (2010: 1,577 million). Debt, net of cash and cash equivalents, is a non-GAAP financial measure that is used by management and investors to measure the Company's overall net indebtedness and to assess the Company's financing risk as measured by its gearing ratio (debt, net of cash and cash equivalents, to total equity). Our gearing ratio was 19.3% at the end of 2011 versus 3.0% at the end of 2010. See Liquidity and Capital Resources Consolidated Balance Sheet and Debt below and Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

### Impacts from generic competition

Our flagship products experienced sales erosion in 2011 due to generic competition. While it is not possible to state with certainty what sales levels would have been achieved in the absence of generic competition, it is possible to estimate the sales impact of generic competition for each product.

By comparing 2011 and 2010 net sales figures included at Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010, competition from generics represented a 2.2 billion loss in net sales in 2011 (at constant exchange rates), or 2.3 billion on a reported basis. The table below presents the detailed impact by product.

( million)	2011	2010	Change on a	Change on a
Product	Reported	Reported	reported basis	reported basis
				(%)
Plavix® Western Europe	414	641	(227)	-35.4%
Aprovel® Western Europe	753	825	(72)	-8.7%
Taxotere® Western Europe	189	709	(520)	-73.3%
Allegra® U.S.	3	147	(144)	-98.0%
Eloxatin® U.S.	806	172	+634	+368.6%
Lovenox® U.S.	633	1,439	(806)	-56.0%
Xyzal® U.S.	13	127	(114)	-89.8%
Ambien® U.S.	82	443	(361)	-81.5%
Xatral® U.S.	75	155	(80)	-51.6%
Nasacort® U.S.	54	130	(76)	-58.5%
Taxotere® U.S.	243	786	(543)	-69.1%
<b>Total</b>	<b>3,265</b>	<b>5,574</b>	<b>(2,309)</b>	<b>-41.4%</b>

We expect erosion from generic competition to continue in 2012, with a negative impact on net income. The following products are expected to be impacted by generics in 2012:

products for which new generic competition can reasonably be expected in 2012 based on the expiration dates or patent or other regulatory exclusivity: Plavix® and Avapro® in the U.S (sales not consolidated by Sanofi), Myslee® in Japan, and possibly Allegra® in Japan in the second half of the year provided that the generic manufacturers get marketing approval;

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products for which generics competition started during 2011, and for which generic competition should continue in 2012: Taxotere<sup>®</sup>, Xatral<sup>®</sup> and Nasacort<sup>®</sup> in the U.S.; and Aprovel<sup>®</sup> in Western Europe;

products which already faced generic competition as of January 1, 2011, but for which 2012 sales can reasonably be expected to be further eroded: Plavix<sup>®</sup>, Eloxatin<sup>®</sup> and Taxotere<sup>®</sup> in Europe; and Lovenox<sup>®</sup>, Ambien<sup>®</sup>, Xyzal<sup>®</sup> and Eloxatin<sup>®</sup> in the U.S;

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A special case is Eloxatin<sup>®</sup> in the U.S., which was subject to generic competition for part of 2010 until a court ruling prevented further sales of unauthorized generics from June 2010 till August 9, 2012. Wholesalers worked down their inventories of generic products in the second half of 2010 and in the first half of 2011.

Aggregate 2011 consolidated net sales generated by all the products in the specific countries where generic competition exists or is expected in 2012, excluding Plavix<sup>®</sup> and Avapro<sup>®</sup> in the U.S., totaled 4,014 million, including 1,909 million in the U.S., 1,356 million in Europe and 749 million (Allegra<sup>®</sup> and Myslee<sup>®</sup>) in Japan. The negative impact on our 2012 net sales could be estimated to potentially represent a substantial part of these sales but will depend on a number of factors, such as actual launch dates of generics products in 2012, selling prices of such products, and potential litigation outcomes.

In addition, the loss of Plavix<sup>®</sup> and Avapro<sup>®</sup> exclusivity in the U.S. in 2012 is anticipated to impact our 2012 net income by around 1.4 billion compared to 2011. Net sales for Plavix<sup>®</sup> and Avapro<sup>®</sup> in the U.S. are not consolidated by Sanofi, however they impact Sanofi's net income (see Financial Presentation of Alliances - Alliance Arrangements with Bristol-Myers Squibb - below).

## **Purchase Accounting Effects**

Our results of operations and financial condition for the years ended December 31, 2011, December 31, 2010 and December 31, 2009 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions, mainly our acquisition of Genzyme on April 4, 2011.

The Aventis acquisition has given rise to significant amortization ( 1,788 million in 2011, 3,070 million in 2010, and 3,175 million in 2009) and impairment of intangible assets (reversal of 34 million in 2011 and charges of 127 million in 2010 and 344 million in 2009). The Genzyme acquisition has given rise to new amortization of intangible assets in 2011 ( 709 million).

In order to isolate the impact of these and certain other items, we use as an evaluation tool a non-GAAP financial measure that we refer to as business net income. For a further discussion and definition of business net income, see Business Net Income - below. For consistency of application of this principle, business net income also takes into account the impact of our subsequent acquisitions.

Business net income for the years ended December 31, 2011, 2010 and 2009 is presented in Business Net Income - below.

## **Sources of Revenues and Expenses**

*Revenue.* Revenue arising from the sale of goods is presented in the income statement under Net sales. Net sales comprise revenue from sales of pharmaceutical products, human vaccines, animal health products and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates described above are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.14. to our consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products and human vaccines directly,

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through alliances, and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the overall level of sales of the products and on the arrangements governing those alliances. For more information about our alliances, see [Financial Presentation of Alliances](#) below. When we sell products through licensees, we receive royalty income that we record in [Other revenues](#). See [Note C](#) to the consolidated financial statements included at [Item 18](#) of this annual report.

*Cost of Sales.* Our cost of sales consists primarily of the cost of purchasing active ingredients and raw materials, labor and other costs relating to our manufacturing activities, packaging materials, payments made under licensing agreements and distribution costs. We have license agreements under which we distribute products that are patented by other companies and license agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in cost of sales, and when we receive royalties, we record them in [Other revenues](#) as discussed above.

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*Operating Income.* Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. For our business segments, we also measure our results of operations through an indicator referred to as Business Operating Income, which we describe below under Segment Information Business Operating Income of Segments.

## **Segment Information**

### *Operating Segments*

In accordance with IFRS 8 Operating Segments, we have defined our segments as Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health. Our other identified segments are categorized as Other.

The Pharmaceuticals segment covers research, development, production and marketing activities relating to pharmaceutical products, including activities acquired with Genzyme. Sanofi's pharmaceuticals portfolio consists of flagship products, plus a broad range of prescription medicines, generic medicines, and consumer health products. This segment also includes all associates and joint ventures with pharmaceutical business activities, in particular the entities majority owned by BMS. See Financial Presentation of Alliances below.

The Vaccines segment is wholly dedicated to vaccines, including research, development, production and marketing. This segment includes our Sanofi Pasteur MSD joint venture with Merck & Co., Inc. in Europe.

The Animal Health segment comprises the research, development, production and marketing activities of Merial, which offers a complete range of medicines and vaccines for a wide variety of animal species.

The Other segment includes all activities that do not qualify as reportable segments under IFRS 8 Operating Segments. In particular, this segment includes our interest in the Yves Rocher group until the date of loss of significant influence (November 2011) (see note D.6. to our consolidated financial statements included at Item 18 of this annual report), and the effects of retained commitments in respect of divested businesses.

Inter-segment transactions are not material.

### *Business Operating Income of Segments*

We report segment results on the basis of Business Operating Income. This indicator, adopted in accordance with IFRS 8, is used internally to measure operational performance and to allocate resources.

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Business Operating Income is derived from Operating income, adjusted as follows:

the amounts reported in the line items Restructuring costs, Fair value remeasurement of contingent consideration liabilities and Other gains and losses, and litigation are eliminated;

amortization and impairment losses charged against intangible assets (other than software) are eliminated;

the share of profits/losses from associates and joint ventures is added;

the share attributable to non-controlling interests is deducted;

other acquisition-related effects (primarily, the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated; and

restructuring costs relating to associates and joint ventures are eliminated.

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The following table presents our Business Operating Income for the year ended December 31, 2011.

( million)	Pharmaceuticals	Vaccines	Animal Health	Other	Total
<b>Net sales</b>	<b>27,890</b>	<b>3,469</b>	<b>2,030</b>		<b>33,389</b>
Other revenues	1,622	25	22		1,669
Cost of sales	(8,368)	(1,404)	(654)		(10,426)
Research and development expenses	(4,101)	(564)	(146)		(4,811)
Selling and general expenses	(7,376)	(542)	(617)	1	(8,536)
Other operating income and expenses	(13)		(7)	24	4
Share of profit/(loss) of associates and joint ventures	1,088	1		13	1,102
Net income attributable to non-controlling interests	(246)		(1)		(247)
<b>Business operating income</b>	<b>10,496</b>	<b>985</b>	<b>627</b>	<b>36</b>	<b>12,144</b>

The following table presents our Business Operating Income for the year ended December 31, 2010.

( million)	Pharmaceuticals	Vaccines	Animal Health <sup>(1)</sup>	Other	Total
<b>Net sales</b>	<b>26,576</b>	<b>3,808</b>	<b>1,983</b>		<b>32,367</b>
Other revenues	1,623	28	18		1,669
Cost of sales	(7,316)	(1,371)	(615)		(9,302)
Research and development expenses	(3,884)	(517)	(155)		(4,556)
Selling and general expenses	(6,962)	(603)	(604)	(2)	(8,171)
Other operating income and expenses	177	14	(6)	(108)	77
Share of profit/(loss) of associates and joint ventures	1,009	19		8	1,036
Net income attributable to non-controlling interests	(258)	1			(257)
<b>Business operating income</b>	<b>10,965</b>	<b>1,379</b>	<b>621</b>	<b>(102)</b>	<b>12,863</b>

<sup>(1)</sup> The results of operations of Merial, which was previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separated businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).

The following table presents our Business Operating Income for the year ended December 31, 2009.

( million)	Pharmaceuticals	Vaccines	Animal Health <sup>(1)</sup>	Other	Total
<b>Net sales</b>	<b>25,823</b>	<b>3,483</b>	<b>479</b>		<b>29,785</b>
Other revenues	1,412	31	4		1,447
Cost of sales	(6,527)	(1,326)	(176)		(8,029)
Research and development expenses	(4,091)	(491)	(46)		(4,628)
Selling and general expenses	(6,762)	(561)	(146)	(2)	(7,471)
Other operating income and expenses	387	(3)	(5)	1	380
Share of profit/(loss) of associates and joint ventures	792	41	178 <sup>(2)</sup>	8	1,019
Net income attributable to non-controlling interests	(426)	(1)			(427)
<b>Business operating income</b>	<b>10,608</b>	<b>1,173</b>	<b>288</b>	<b>7</b>	<b>12,076</b>

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- (1) The results of operations of Merial, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separated businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).*
- (2) Including Merial until September 17, 2009.*



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**Business Net Income**

In addition to net income, we use a non-GAAP financial measure that we refer to as **business net income** to evaluate our Group's performance. Business net income, which is defined below, represents the aggregate business operating income of all of our operating segments, less net financial expenses and the relevant income tax charges. We believe that this non-GAAP financial measure allows investors to understand the performance of our Group because it segregates the results of operations of our current business activities, as opposed to reflecting the impact of past transactions such as acquisitions.

Our management uses business net income to manage and to evaluate our performance, and we believe it is appropriate to disclose this non-GAAP financial measure, as a supplement to our IFRS reporting, in order to assist investors in analyzing the factors and trends affecting our business performance. Our management also intends to use business net income as the basis for proposing the dividend policy for the Group. Accordingly, management believes that an investor's understanding of trends in our dividend policy is enhanced by disclosing business net income.

We have also decided to report **business earnings per share**. Business earnings per share is a specific non-GAAP financial measure, which we define as business net income divided by the weighted average number of shares outstanding. Our management intends to give earnings guidance based on business earnings per share. We also present business earnings per share on a diluted basis.

Business net income is defined as **Net income attributable to equity holders of Sanofi**, determined under IFRS, excluding (i) amortization of intangible assets; (ii) impairment of intangible assets; (iii) fair value remeasurement of contingent consideration liabilities; (iv) other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures); (v) restructuring costs (including restructuring costs relating to associates and joint ventures), (vi) other gains and losses, and litigation; (vii) the impact of the non-depreciation of the property, plant and equipment of Merial in 2010 and starting September 18, 2009 (in accordance with IFRS 5); (viii) the tax effect related to the items listed in (i) through (vii); as well as (ix) the effects of major tax disputes and, as an exception for 2011, the retroactive effect (2006-2010) on the tax liability resulting from the agreement signed on December 22, 2011 by France and the United States on transfer prices (APA-Advance Pricing Agreement), for which the amount is deemed to be significant, and (x) the share of non-controlling interests in items (i) through (ix). Items (iii), (v) and (vi) correspond to those reported in the income statement line items **Restructuring costs**, **Fair value remeasurement of contingent consideration liabilities**, and **Other gains and losses, and litigation**, as defined in Notes B.19. and B.20. to our consolidated financial statements.

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The following table reconciles our business net income to Net income attributable to equity holders of Sanofi for the years ended December 31, 2011, 2010 and 2009:

( million)	2011	2010 <sup>(1)</sup>	2009 <sup>(1)</sup>
<b>Business net income</b>	<b>8,795</b>	<b>9,215</b>	<b>8,629</b>
(i) Amortization of intangible assets	(3,314)	(3,529)	(3,528)
(ii) Impairment of intangible assets	(142)	(433)	(372)
(iii) Fair value remeasurement of contingent consideration liabilities	15		
(iv) Expenses arising from the impact of acquisitions on inventories <sup>(2)</sup>	(476)	(142)	(90)
(v) Restructuring costs	(1,314)	(1,384)	(1,080)
(vi) Other gains and losses, and litigation <sup>(3)</sup>	(327)	(138)	
(vii) Impact of the non-depreciation of the property, plant and equipment of Merial (IFRS 5)		77	21
(viii) Tax effects on the items listed above, comprising:	1,905	1,856	1,644
<i>amortization of intangible assets</i>	<i>1,178</i>	<i>1,183</i>	<i>1,130</i>
<i>impairment of intangible assets</i>	<i>37</i>	<i>143</i>	<i>136</i>
<i>fair value remeasurement of contingent consideration liabilities</i>	<i>34</i>		
<i>expenses arising from the impact of acquisitions on inventories</i>	<i>143</i>	<i>44</i>	<i>24</i>
<i>restructuring costs</i>	<i>399</i>	<i>466</i>	<i>360</i>
<i>other gains and losses, and litigation</i>	<i>114</i>	<i>46</i>	
<i>non-depreciation of property, plant and equipment of Merial (IFRS 5)</i>		<i>(26)</i>	<i>(6)</i>
(iv)/(ix) Other tax items <sup>(4)</sup>	577		106
(x) Share of items listed above attributable to non-controlling interests	6	3	1
(iv)/(v) Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures <sup>(5)</sup>	(32)	(58)	(66)
<b>Net income attributable to equity holders of Sanofi</b>	<b>5,693</b>	<b>5,467</b>	<b>5,265</b>

<sup>(1)</sup> The results of operations of Merial, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separate businesses operating independently (see Notes D.2. and D.8.1. to our consolidated financial statements included at Item 18 of this annual report).

<sup>(2)</sup> This line comprises the workdown of inventories remeasured at fair value at the acquisition date.

<sup>(3)</sup> See Note D.28. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(4)</sup> In 2011, related to Advance Pricing Agreement impact for 349 million and 228 million reflecting a decrease in deferred tax liabilities related to the remeasurement of intangible assets following changes in tax laws. In 2009: reversal of deferred taxes following ratification of the Franco-American Treaty.

<sup>(5)</sup> This line shows the portion of major restructuring costs incurred by associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill).

The most significant reconciliation items in the table above relate to the purchase accounting effect of our acquisitions, particularly the amortization and impairment of intangible assets. We believe that excluding these non-cash charges enhances an investor's understanding of our underlying economic performance because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

The purchase-accounting effects on net income primarily relate to:

charges to cost of sales resulting from the workdown of acquired inventories that was written up to fair value, net of tax;

charges related to the impairment of goodwill; and

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charges related to the amortization and impairment of intangible assets, net of tax and non-controlling interests.

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We believe (subject to the limitations described below) that disclosing business net income enhances the comparability of our operating performance, for the following reasons:

the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of finite-lived intangible assets) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;

the elimination of selected items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, gains and losses on disposals of non-current assets and costs and provisions associated with major litigation, improves comparability from one period to the next; and

the elimination of restructuring costs relating to the implementation of our transformation strategy enhances comparability because these costs are directly, and only, incurred in connection with transformation processes such as the rationalization of our research and development structures.

We remind investors, however, that business net income should not be considered in isolation from, or as a substitute for, net income attributable to equity holders of Sanofi reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, and our other publicly filed reports, carefully and in their entirety.

There are material limitations associated with the use of business net income as compared to the use of IFRS net income attributable to equity holders of Sanofi in evaluating our performance, as described below:

The results presented by business net income cannot be achieved without incurring the following costs that the measure excludes:

*Amortization of intangible assets.* Business net income excludes the amortization charges related to intangible assets. Most of these amortization charges relate to intangible assets that we have acquired. Although amortization is a non-cash charge, it is important for investors to consider it because it represents an allocation in each reporting period of a portion of the purchase price that we paid for certain intangible assets that we have acquired through acquisitions. For example, in connection with our acquisition of Aventis in 2004, we paid an aggregate of 31,279 million for these amortizable intangible assets (which, in general, were to be amortized over their useful lives, which represented an average amortization period of eight years) and 5,007 million for in-progress research & development. More recently, in connection with our acquisition of Genzyme in April 2011, we paid an aggregate of 7,877 million for amortizable intangible assets (average amortization period of eight years and a half) and 2,148 million for in-progress research & development. A large part of our revenues could not be generated without owning acquired intangible assets.

*Restructuring costs.* Business net income does not reflect restructuring costs even though it does reflect the benefits of the optimization of our activities, such as our research and development activities, much of which we could not achieve in the absence of restructuring costs.

In addition, the results presented by business net income are intended to represent the Group's underlying performance, but items such as gains and losses on disposals and provisions associated with major litigation may recur in future years.

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We compensate for the above-described material limitations by using business net income only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in business net income. In addition, subject to applicable law, we may in the future decide to report additional non-GAAP financial measures which, in combination with business net income, may compensate further for some of the material limitations described above.

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In determining the level of future dividend payments, and in analyzing dividend policy on the basis of business net income, our management intends to take into account the fact that many of the adjustments reflected in business net income have no effect on the underlying amount of cash available to pay dividends. However, although the adjustments relating to the elimination of the effect of the purchase accounting treatment of the Aventis acquisition and other acquisitions represent non-cash charges, the adjustments relating to restructuring costs represent significant cash charges in the periods following the closing of the acquisition.

This Item 5 contains a discussion and analysis of business net income on the basis of consolidated financial data. Because our business net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

## **Presentation of Net Sales**

In the discussion below, we present our consolidated net sales for 2011, 2010 and 2009. We break down our net sales among various categories, including by business segment, product and geographic region. We refer to our consolidated net sales as reported sales.

In addition to reported sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in group structure.

When we refer to changes in our net sales at constant exchange rates, we exclude the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period. See Note B.2 to our consolidated financial statements for further information relating to the manner in which we translate into euros transactions recorded in other currencies.

When we refer to our net sales on a constant structure basis, we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

by including sales from an entity or with respect to product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we made the acquisition;

similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and

for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

A reconciliation of our reported net sales to our net sales at constant exchange rates is provided at Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010 Net Sales and at Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 Net Sales below.

**Financial Presentation of Alliances**

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our two principal alliances is useful to an understanding of our financial statements.

The financial impact of the alliances on the Company's income statement is described in **Results of Operations** **Year Ended December 31, 2011 Compared with Year Ended December 31, 2010** and **Year Ended December 31, 2010 Compared with Year Ended December 31, 2009**, in particular in **Net sales**, **Other Revenues**, **Share of Profit/Loss of Associates and Joint Ventures** and **Net Income Attributable to Non-Controlling Interests**.

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### ***Alliance Arrangements with Bristol-Myers Squibb***

Our revenues, expenses and operating income are affected significantly by the presentation of our alliance with Bristol-Myers Squibb (BMS) in our consolidated financial statements.

There are three principal marketing arrangements that are used:

*Co-marketing.* Under the co-marketing system, each company markets the products independently under its own brand names. We record our own sales and related costs in our consolidated financial statements.

*Exclusive Marketing.* Under the exclusive marketing system, one company has the exclusive right to market the products. We record our own sales and related costs in our consolidated financial statements.

*Co-promotion.* Under the co-promotion system, the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name. The accounting treatment of the co-promotion agreement depends upon who has majority ownership and operational management in that territory, as discussed below.

The alliance arrangements include two royalty streams that are applied on a worldwide basis (excluding Japan and other opt out countries), regardless of the marketing system and regardless of which company has majority ownership and operational management:

*Discovery Royalty.* As inventor of the two molecules, we earn an adjustable discovery royalty on part of Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Karvezide<sup>®</sup> and Plavix<sup>®</sup>/Iscover<sup>®</sup> sold in alliance countries regardless of the marketing system. The discovery royalty earned in territories under operational management of BMS is reflected in our consolidated income statement in Other revenues.

*Development Royalty.* In addition to the discovery royalty, we and BMS are each entitled to a development royalty related to certain know-how and other intellectual property in connection with sales of Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Karvezide<sup>®</sup> and Plavix<sup>®</sup>/Iscover<sup>®</sup>.

We record development royalties paid to BMS in our consolidated income statement as an increase to our cost of sales in countries where we consolidate sales of the products. We record development royalties that we receive as other revenues in countries where BMS consolidates sales of the products.

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world (excluding Japan). In Japan, Aprovel<sup>®</sup> has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd since June 2008. Our alliance with BMS does not cover distribution rights to Plavix<sup>®</sup> in Japan, which is marketed by Sanofi.

*Territory under our operational management.* In the territory under our operational management, the marketing arrangements and recognition of operations by the Group are as follows:



we use the co-promotion system for most of the countries in Western Europe for Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Karvezide<sup>®</sup> and Plavix<sup>®</sup>/Iscover<sup>®</sup> and for certain Asian countries for Plavix<sup>®</sup>/Iscover<sup>®</sup>. We record 100% of all alliance revenues and expenses in our consolidated financial statements. We also record, as selling and general expenses, payments to BMS for the cost of BMS's personnel involved in the promotion of the products. BMS's share of the operating income of the alliances is recorded as non-controlling interests ;

we use the co-marketing system in Germany, Spain and Greece for both Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Karvezide<sup>®</sup> and Plavix<sup>®</sup>/Iscover<sup>®</sup> and in Italy for Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Karvezide<sup>®</sup>; and

we have the exclusive right to market Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Karvezide<sup>®</sup> and Plavix<sup>®</sup>/Iscover<sup>®</sup> in Eastern Europe, Africa, the Middle East, and certain Asian countries (excluding Japan); we have the exclusive right to market Aprovel<sup>®</sup> in Scandinavia and Ireland, and Plavix<sup>®</sup> in Malaysia.

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*Territory under BMS operational management.* In the territory under BMS operational management, the marketing arrangements and recognition of operations by the Group are as follows:

we use the co-promotion system in the United States, Canada and Puerto Rico, where the products are sold through the alliances under the operational management of BMS. With respect to Avapro<sup>®</sup> (the brand name used in the United States for Aprovel<sup>®</sup>) and Plavix<sup>®</sup>, we record our share of the alliance's operating income under "share of profit/loss of associates and joint ventures". We also record payments from BMS for the cost of our personnel in connection with the promotion of the product as a deduction from our selling and general expenses;

we use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix<sup>®</sup>/Iscover<sup>®</sup> and Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Karvezide<sup>®</sup> and in Colombia for Plavix<sup>®</sup>/Iscover<sup>®</sup>; and

we have the exclusive right to market the products in certain other countries of Latin America.

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we also earn revenues from the sale of the active ingredients for the products to BMS or such entities, which we record as "Net sales" in our consolidated income statement.

***Alliance arrangements with Warner Chilcott (previously with Procter & Gamble Pharmaceuticals)***

Our agreement with Warner Chilcott (the Alliance Partner) covers the worldwide development and marketing arrangements of Actonel<sup>®</sup> except Japan for which we hold no rights. Until October 30, 2009, this agreement was between Sanofi and Procter & Gamble Pharmaceuticals (P&G). Since the sale by P&G of its pharmaceutical business to Warner Chilcott on October 30, 2009, Actonel<sup>®</sup> has been marketed in collaboration with Warner Chilcott. The local marketing arrangements may take various forms.

*Co-promotion*, whereby sales resources are pooled but only one of the two parties to the alliance agreement (Sanofi or the Alliance Partner) invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. The Alliance Partner sells the product and incurs all of the related costs in France and Canada. This co-promotion scheme formerly included Germany, Belgium and Luxembourg until December 31, 2007, the Netherlands until March 31, 2008, and the United States and Puerto Rico until March 31, 2010. We recognize our share of revenues under the agreement in our income statement as a component of operating income in the line item "Other operating income". Since April 1, 2010, we have received royalties from the Alliance Partner on sales made by the Alliance Partner in the United States and Puerto Rico. In the secondary co-promotion territories (the United Kingdom until December 31, 2008, Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia), we sell the product and recognize all the revenues from sales of the product along with the corresponding expenses. The share due to the Alliance Partner is recognized in "Cost of sales";

*Co-marketing*, which applies in Italy whereby each party to the alliance agreement sells the product in the country under its own brand name, and recognizes all revenues and expenses from its own operations in its respective income statement. Each company also markets the product independently under its own brand name in Spain, although Spain is not included in the co-marketing territory;

*Warner Chilcott only territories:* the product has been marketed by the Alliance Partner independently in Germany, Belgium and Luxembourg since January 1, 2008, in the Netherlands since April 1, 2008 and in the United Kingdom since January 1, 2009. We recognize our share of revenues under the alliance agreement in "Other operating income"; and

*Sanofi only territories:* we have exclusive rights to sell the product in all other territories. We recognize all revenues and expenses from our own operations in our income statement, but in return for these exclusive rights we pay the Alliance Partner a royalty based on actual sales. This royalty is recognized in Cost of sales .

In 2010, Sanofi and Warner Chilcott began negotiations on the future of their alliance arrangements. In an arbitration proceeding, an arbitration panel decided on July 14, 2011 that the termination by Warner Chilcott of an ancillary agreement did not lead to the termination of the Actonel® Alliance. Pursuant to this decision, the alliance will remain in effect until January 1, 2015.

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### **Impact of Exchange Rates**

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2011, we earned 29.8% of our net sales in the United States. A decrease in the value of the U.S. dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A decrease in the value of the U.S. dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our alliance with BMS in the United States, which is under the operational management of BMS, as described at Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb above.

For a description of positions entered into to manage operational foreign exchange risks as well as our hedging policy, see Item 11. Quantitative and Qualitative Disclosures about Market Risk, and Item 3. Key Information D. Risk Factors Risks Related to Financial Markets Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.

### **Divestments**

On December 19, 2011 Sanofi sold the Dermik dermatology business to Valeant Pharmaceuticals International Inc., for 321 million (see Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report).

There were no material divestments in 2010 or 2009.

### **Acquisitions**

The principal acquisitions during 2011 are described below:

In February 2011, Sanofi completed the acquisition of 100% of the share capital of BMP Sunstone Corporation (BMP Sunstone), a pharmaceutical company that develops a portfolio of branded pharmaceutical and healthcare products in China. See Note D.1.2. to our consolidated financial statements included at Item 18 of this annual report.

In April 2011, Sanofi acquired Genzyme Corporation (Genzyme), a major biotechnology company headquartered in Cambridge, Massachusetts (United States), with primary areas of focus in rare diseases, renal endocrinology, oncology and biosurgery. In 2011, Genzyme generated full-year net sales of 3.1 billion, out of which 2.4 billion were consolidated by Sanofi as from the acquisition date. The transaction was completed in accordance with the terms of the public exchange offer at a price of \$74 in cash plus the issuance to Genzyme shareholders of one contingent value right (CVR) per share. Total purchase price amounted to 14.8 billion. The provisional purchase price allocation is disclosed in Note D.1.1. to our consolidated financial statements included at Item 18 of this annual report.

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In October 2011, Sanofi acquired Topaz Pharmaceuticals Inc. (Topaz), a U.S. pharmaceutical research company that developed an innovative anti-parasitic product for treating head lice. An upfront payment of \$35 million was made on completion of the transaction. According to the agreement, future milestone payments may be made upon market approval and depending on the achievement of sales targets. See Note D.1.2. to our consolidated financial statements included at Item 18 of this annual report. The total amount of payments (including the upfront payment) could reach \$207.5 million.

In November 2011, Sanofi acquired the business of Universal Medicare Private Limited (Universal), a major producer of nutraceuticals in India. An upfront payment of 83 million was made on completion of the transaction. See Note D.1.2. to our consolidated financial statements included at Item 18 of this annual report.

In December 2011, Sanofi co-invested in Warp Drive Bio, an innovative start-up biotechnology company, along with two venture capital firms, Third Rock Ventures (TRV) and Greylock Partners. Warp Drive Bio is an

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innovative biotechnology company, focusing on proprietary genomic technology to discover drugs of natural origin. Under the terms of the agreement, Sanofi and TRV / Greylock will invest in Warp Drive Bio at parity. Total program funding over the first five years could amount to up to \$125 million, including an equity investment of up to \$75 million.

The principal acquisitions during 2010 are described below:

In February 2010, Sanofi acquired the U.S.-based company Chattem, Inc. (Chattem) by successfully completing a cash tender offer leading to the acquisition of 100% of the share capital. Chattem is a major consumer health player in the United States, producing and distributing branded consumer health products, toiletries and dietary supplements across various market segments. Chattem manages the Allegra® brand, and acts as the platform for Sanofi over-the-counter and consumer healthcare products in the United States. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

In April 2010, Sanofi acquired a controlling interest in the capital of Bioton Vostok, a Russian insulin manufacturer. Under the terms of the agreement, put options were granted to non-controlling interests. See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

In May 2010, Sanofi formed a new joint venture with Nichi-Iko Pharmaceuticals Co., Ltd (Nichi-Iko), a leading generics company in Japan, to expand generics activities in the country. In addition to forming this joint venture, Sanofi took a 4.66% equity interest in the capital of Nichi-Iko.

In June 2010, Sanofi acquired 100% of the share capital of Canderm Pharma Inc. (Canderm), a privately-held leading Canadian skincare company distributing cosmeceuticals and dermatological products. Canderm generated net sales of 24 million Canadian dollars in 2009.

In July 2010, Sanofi acquired 100% of the share capital of TargeGen, Inc. (TargeGen), a U.S. biopharmaceutical company developing small molecule kinase inhibitors for the treatment of certain forms of leukemia, lymphoma and other hematological malignancies and blood disorders. An upfront payment of \$75 million was made on completion of the transaction. Future milestone payments may be made at various stages in the development of TG 101348, TargeGen's principal product candidate. The total amount of payments (including the upfront payment) could reach \$560 million. See Note D.1. and Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

In August 2010, Sanofi acquired 100% of the share capital of Nepentes S.A. (Nepentes), a Polish manufacturer of pharmaceuticals and dermocosmetics, for a consideration of PLN 425 million ( 106 million).

In October 2010, Sanofi Pasteur acquired 100% of the share capital of VaxDesign Corporation (VaxDesign), a privately-held U.S. biotechnology company which has developed a technology reproducing in vitro models of the human immune system, that can be used to select the best candidate vaccines at the pre-clinical stage. Under the terms of the agreement, an upfront payment of \$55 million was made upon closing of the transaction, and a further \$5 million will be payable upon completion of a specified development milestone.

In October 2010, Sanofi acquired a 60% equity interest in the Chinese consumer healthcare company Hangzhou Sanofi Minsheng Consumer Healthcare Co. Ltd, in partnership with Minsheng Pharmaceutical Co., Ltd ( Minsheng ). Minsheng was also granted a put option over the

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remaining shares not held by Sanofi. See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

The principal acquisitions during 2009 are described below:

On September 17, 2009, and further to the agreement signed on July 29, 2009, Sanofi completed the acquisition of the interest held by Merck & Co., Inc. (Merck) in Merial Limited (Merial) for consideration of \$4 billion in cash. Founded in 1997, Merial was previously held jointly (50/50) by Merck and Sanofi. Merial is one of the world's leading animal health companies, with annual sales of \$2.6 billion in 2009 and 2010. With effect from September 17, 2009, Sanofi has held 100% of the shares of Merial and has exercised exclusive control over the company.

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In connection with the agreement signed on July 29, 2009, Sanofi had also signed an option contract giving it the possibility, once the Merck/Schering-Plough merger would be complete, to combine the Merck-owned Intervet/Schering-Plough Animal Health business with Merial in a joint venture to be held 50/50 by Merck and Sanofi. Because of the high probability of the option being exercised as of year-end 2009 and 2010, Merial was treated as an asset held for sale or exchange pursuant to IFRS 5 as of December 31, 2009 and December 31, 2010. On March 8, 2010, Sanofi exercised its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial. However, on March 22, 2011, Merck and Sanofi announced that they had mutually terminated their agreement to form a new animal health joint venture and decided to maintain Merial and Intervet/Schering-Plough as two separate entities, operating independently. This decision was mainly due to the increasing complexity of implementing the proposed transaction. Starting from January 1, 2011, Merial is no longer accounted for separately on the consolidated balance sheet and income statements of Sanofi. Detailed information about the impact of Merial on the consolidated financial statements of Sanofi as of December 31, 2011 is provided in Note D.2. and Note D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

In March 2009, Sanofi successfully closed its offer for Zentiva N.V. (Zentiva). As of December 31, 2009, Sanofi held about 99.1% of Zentiva's share capital. Following the buyout of the remaining non-controlling interests, Sanofi held 100% of Zentiva's share capital as of December 31, 2010. The purchase price was 1,200 million, including acquisition-related costs.

In March 2009, Sanofi acquired Laboratorios Kendrick, one of Mexico's leading manufacturers of generics, with sales of approximately 26 million in 2008.

In April 2009, Sanofi acquired a 100% equity interest in Medley, the third largest pharmaceutical company in Brazil and a leading generics company in that country. The purchase price was 348 million inclusive of acquisition-related costs.

In April 2009 Sanofi acquired 100% of BiPar Sciences, Inc. (BiPar), a U.S. biopharmaceutical company developing novel tumor-selective approaches for the treatment of different types of cancers. The purchase price was in large part contingent on the achievement (regarded as probable) of milestones related to the development of BSI-201, and could reach \$500 million. See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

In July 2009, Sanofi completed the acquisition of 100% of the share capital of Helvepharm, a Swiss generics company.

In August 2009, Sanofi took control of Shantha Biotechnics (Shantha), a vaccines company based in Hyderabad (India). As of December 31, 2010, Sanofi held approximately 96.4% of Shantha. The purchase price allocation led to the recognition of intangible assets (excluding goodwill) worth 374 million. This amount includes the acquisitions-date value of the ShanS pentavalent vaccine, which was partially written down in 2010 (see Note D.5. to our consolidated financial statements included at Item 18 of this annual report).

In October 2009, Sanofi acquired 100% of the share capital of Fovea Pharmaceuticals SA, a privately-held French biopharmaceutical research and development company specializing in ophthalmology. The purchase consideration included contingent milestone payments of up to 280 million linked to the development of three products. See Notes D.1. and D.18. to our consolidated financial statements included at Item 18 of this annual report.



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In November 2009, Sanofi completed the acquisition of 100% of the share capital of Laboratoire Oenobiol, one of France's leading players in health and beauty dietary supplements.

**Table of Contents****Results of Operations***Year Ended December 31, 2011 Compared with Year Ended December 31, 2010*

The consolidated income statements for the years ended December 31, 2011 and December 31, 2010 break down as follows:

(under IFRS)		as % of		as % of
( million)	2011	net sales	2010 <sup>(1)</sup>	net sales
<b>Net sales</b>	<b>33,389</b>	<b>100.0%</b>	<b>32,367</b>	<b>100.0%</b>
Other revenues	1,669	5.0%	1,669	5.2%
Cost of sales	(10,902)	(32.7%)	(9,398)	(29.0%)
<b>Gross profit</b>	<b>24,156</b>	<b>72.3%</b>	<b>24,638</b>	<b>76.1%</b>
Research & development expenses	(4,811)	(14.4%)	(4,547)	(14.0%)
Selling & general expenses	(8,536)	(25.6%)	(8,149)	(25.2%)
Other operating income	319		369	
Other operating expenses	(315)		(292)	
Amortization of intangible assets	(3,314)		(3,529)	
Impairment of intangible assets	(142)		(433)	
Fair value remeasurement of contingent consideration liabilities	15			
Restructuring costs	(1,314)		(1,384)	
Other gains and losses, and litigation <sup>(2)</sup>	(327)		(138)	
<b>Operating income</b>	<b>5,731</b>	<b>17.2%</b>	<b>6,535</b>	<b>20.2%</b>
Financial expenses	(552)		(468)	
Financial income	140		106	
<b>Income before tax and associates and joint ventures</b>	<b>5,319</b>	<b>15.9%</b>	<b>6,173</b>	<b>19.1%</b>
Income tax expense	(455)		(1,430)	
Share of profit/(loss) of associates and joint ventures	1 070		978	
<b>Net income</b>	<b>5,934</b>	<b>17.8%</b>	<b>5,721</b>	<b>17.7%</b>
Net income attributable to non-controlling interests	241		254	
<b>Net income attributable to equity holders of Sanofi</b>	<b>5,693</b>	<b>17.1%</b>	<b>5,467</b>	<b>16.9%</b>
Average number of shares outstanding (million)	1,321.7		1,305.3	
Average number of shares outstanding after dilution (million)	1,326.7		1,308.2	
Basic earnings per share (in euros)	4.31		4.19	
Diluted earnings per share (in euros)	4.29		4.18	

<sup>(1)</sup> The results of operations of Merial, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with IFRS 5.36., following the announcement that Merial and Intervet/Schering-Plough will be maintained as separate businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).

<sup>(2)</sup> See Note B.20.2. to our consolidated financial statements included at Item 18 of this annual report.

*Net Sales*

Net sales for the year ended December 31, 2011 totaled 33,389 million, up 3.2% on 2010. The unfavorable currency fluctuation of 2.1 points was primarily the result of the U.S. dollar's depreciation against the euro. At constant exchange rates, and after taking account of changes in structure (mainly the consolidation of Genzyme from April 2011), net sales were up 5.3% year-on-year.



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Excluding Genzyme, the Group's net sales were down 2.6% in 2011 at constant exchange rates, a reflection of the loss in sales associated with competition from generics and the impacts of austerity measures in the European Union. Excluding both Genzyme and sales of A/H1N1 vaccines, the Group's net sales were down 1.2% at constant exchange rates.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2011 and December 31, 2010 to our net sales at constant exchange rates:

			Change
( million)	2011	2010 <sup>(1)</sup>	(%)
<b>Net sales</b>	<b>33,389</b>	<b>32,367</b>	<b>+3.2%</b>
Effect of exchange rates	704		
<b>Net sales at constant exchange rates</b>	<b>34,093</b>	<b>32,367</b>	<b>+5.3%</b>

<sup>(1)</sup> Net sales of Meril are included. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report.

Our net sales comprise the net sales generated by our Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health businesses.

The following table breaks down our 2011 and 2010 net sales by business segment:

			Change on a	Change at
( million)	2011	2010	reported basis	constant
	Reported	Reported	(%)	exchange rates
			(%)	(%)
Pharmaceuticals	27,890	26,576	+4.9%	+6.7%
Vaccines	3,469	3,808	-8.9%	-5.5%
Animal Health	2,030	1,983	+2.4%	+4.3%
<b>Total</b>	<b>33,389</b>	<b>32,367</b>	<b>+3.2%</b>	<b>+5.3%</b>

*Net Sales by Product - Pharmaceuticals*

Net sales generated by our Pharmaceuticals segment were 27,890 million in 2011, up 4.9% on a reported basis and 6.7% at constant exchange rates. This change reflects the positive impact from the Genzyme consolidation, the negative impact from the competition of generics on sales of Lovenox<sup>®</sup>, Ambien<sup>®</sup> CR and Taxotere<sup>®</sup> in the United States, Plavix<sup>®</sup> and Taxotere<sup>®</sup> in the European Union, as well as the effects of healthcare reform in the U.S. and austerity measures in Europe. Excluding Genzyme, our Pharmaceuticals segment posted net sales of 25,495 million, a drop of 4.1% on a reported basis and 2.7% at constant exchange rates.

*Flagship Products*

Our flagship products (Lantus<sup>®</sup> and other products in the Diabetes business, Lovenox<sup>®</sup>, Plavix<sup>®</sup>, Taxotere<sup>®</sup>, Aprovel<sup>®</sup>/CoAprovel<sup>®</sup>, Eloxatin<sup>®</sup>, Multaq<sup>®</sup> and Jevtana<sup>®</sup>) are discussed below. Sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> are discussed further below under [Worldwide Presence of Plavix and Aprovel](#) .

Net sales in the Diabetes business were 4,684 million, up 12.0% at constant exchange rates, bolstered by the growth of Lantus<sup>®</sup>.

**Lantus<sup>®</sup>**, the world's leading diabetes brand (source: IMS 2011 sales), posted a 15.0% increase in net sales at constant exchange rates in 2011 to 3,916 million. This change is a result of the sharp growth in Emerging Markets (26.0% at constant exchange rates), especially in China (61.7%) and Brazil (29%), as well as solid performance in the United States (14.6%) and Japan (19.5%). In Western Europe, growth was more moderate (6.4%), which reflected the pricing pressures specifically in Germany.

Net sales of the rapid-acting insulin analog **Apidra<sup>®</sup>** advanced by 9.6% at constant exchange rates in 2011 to 190 million, led by solid performances in Japan (87.9% growth) and the United States (11.3% growth). At year-end, sales were impacted negatively by a temporary shortage of Apidra<sup>®</sup> 3ml cartridges.

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**Amaryl**<sup>®</sup> saw net sales decrease by 7.9% at constant exchange rates in 2011 to 436 million, due principally to competition from generics in Japan, and despite an 8.6% increase (at constant exchange rates) in Emerging Markets.

**Lovenox**<sup>®</sup> saw net sales decrease by 23.4% at constant exchange rates in 2011 to 2,111 million, a result of competition from generics in the United States where net sales declined by 54.3% to 633 million. Outside the United States, net sales were up 9.0% at constant exchange rates, to 1,478 million (representing 70.0% of worldwide 2011 sales of Lovenox<sup>®</sup>), posting good performances in Western Europe (up 6.4%) and Emerging Markets (up 14.0%).

**Taxotere**<sup>®</sup> reported net sales of 922 million, down 57.0% at constant exchange rates. This product has faced competition from generics in Western Europe (down 73.6%) and the United States (down 69.2%), although the decline was much less pronounced in Emerging Markets (down 24.6%).

**Eloxatin**<sup>®</sup> net sales rebounded sharply in 2011 by 160.9% at constant exchange rates to 1,071 million, which reflects recovering sales in the United States (806 million in 2011, versus 172 million in 2010), following a court ruling barring manufacturers of generics in the U.S. from selling their unapproved generic versions of oxaliplatin from June 30, 2010.

**Multaq**<sup>®</sup> posted a 56.4% growth in net sales to 261 million at constant exchange rates, achieved primarily in the United States (184 million) and Western Europe (66 million).

**Jevtana**<sup>®</sup>, which has been available in the U.S. market since July 2010, and has become gradually available throughout most of the countries of Western Europe since April 2011, registered 188 million in sales in 2011, 131 million of which was in the United States.

Our other major products are described below.

Net sales of the hypnotic **Stilnox**<sup>®</sup>/**Ambien**<sup>®</sup>/**Myslee**<sup>®</sup> fell by 41.4% at constant exchange rates to 490 million, reflecting competition from Ambien<sup>®</sup> CR generics in the United States. In Japan, Myslee<sup>®</sup> continued to post a solid performance with net sales up 9.2% at constant exchange rates at 284 million.

**Allegra**<sup>®</sup> prescription sales were down 8.6% (at constant exchange rates) to 580 million. In Japan, which represents 80.2% of Allegra<sup>®</sup>'s worldwide sales, net sales totaled 465 million (up 22.1% at constant exchange rates) with the sharp increase in seasonal allergies. A generic has been approved but not yet distributed in Japan. The drop in prescription sales in the United States (98.6% at constant exchange rates) is related to the approval of Allegra<sup>®</sup> as an over-the-counter (OTC) product starting in March 2011 on the U.S. market. Following this approval, we account for U.S. sales of Allegra<sup>®</sup> under CHC and not prescription sales.

**Copaxone**<sup>®</sup> net sales, achieved primarily in Western Europe, fell by 15.4% at constant exchange rates to 436 million, a reflection of the end of the co-promotion agreement with Teva for certain countries, specifically since the end of 2010 in the UK and the end of 2011 in Germany.

The **Consumer Health Care** business posted year-on-year growth of 22.8% at constant exchange rates to 2,666 million, supported by the successful launch of Allegra® as an over-the-counter product in the U.S. in the first quarter of 2011, generating 211 million in net sales for the year (out of a worldwide total of 245 million), and by the performance of Emerging Markets in which net sales have increased by 20.8% at constant exchange rates to 1,225 million. These figures consolidated the consumer health products of Chattem in the United States as of February 2010, and of BMP Sunstone in China as of February 2011.

The **Generics** business reported net sales of 1,746 million in 2011, up 16.2% at constant exchange rates. This growth was underpinned by sales in Emerging Markets (1,092 million, up 14.0% at constant exchange rates), especially in Latin America (up 21.4% at constant exchange rates), and the United States (up 79.4% at constant exchange rates) where Sanofi launched its own approved generics of Ambien® CR, Taxotere® and Lovenox®.

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Net sales of **Genzyme** products in 2011 (since the acquisition date beginning of April) were up 7.7% on a constant structure basis and at constant exchange rates, to 2,395 million. Net sales are recognized as from the acquisition date and comparisons are with the net sales reported by Genzyme in 2010 for the same period.

Net sales of **Cerezyme**<sup>®</sup> were up 11.1% (on a constant structure basis and at constant exchange rates) to 441 million, which reflects the higher production in 2011 following a reduction in availability of the product in 2010 due to manufacturing issues. **Myozyme**<sup>®</sup>/**Lumizyme**<sup>®</sup> posted sharp growth (27.4% on a constant structure basis and at constant exchange rates, to 308 million), bolstered mainly by the performance of Lumizyme<sup>®</sup> in the United States and volume growth worldwide. Growth in **Fabrazyme**<sup>®</sup> sales (9.4% on a constant structure basis and at constant exchange rates, to 109 million) was sparked by the increase in the product's availability following on-going resolution of manufacturing issues. For more information regarding the manufacturing issues related to Cerezyme<sup>®</sup> and Fabrazyme<sup>®</sup> see Item 4 Information on the Company Production and Raw Materials.

**Renagel**<sup>®</sup>/**Renvela**<sup>®</sup> posted net sales of 415 million, up 10.2% on a constant structure basis and at constant exchange rates, associated with growth in the market share in the U.S.

Net sales of **Synvisc**<sup>®</sup> totaled 256 million (up 14.7% on a constant structure basis and at constant exchange rates), supported by the solid performance of **Synvisc One**<sup>®</sup> in the U.S. and Japan.

Net sales of the other products in the portfolio were down 3.4% at constant exchange rates, to 5,773 million. For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Pharmaceutical Products.



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The following table breaks down our 2011 and 2010 net sales for the Pharmaceuticals business by product:

( million)	Product	Indication	2011 Reported	2010 Reported	Change at	
					a reported basis (%)	constant exchange rates (%)
	Lantus®	Diabetes	3,916	3,510	+11.6%	+15.0%
	Apidra®	Diabetes	190	177	+7.3%	+9.6%
	Insuman®	Diabetes	132	133	-0.8%	-0.8%
	Amaryl®	Diabetes	436	478	-8.8%	-7.9%
	Other products	Diabetes	10			
	<b>Sub-total: Diabetes</b>		<b>4,684</b>	<b>4,298</b>	<b>+9.0%</b>	<b>+12.0%</b>
	Lovenox®	Thrombosis	2,111	2,806	-24.8%	-23.4%
	Plavix®	Atherothrombosis	2,040	2,083	-2.1%	-2.9%
	Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	922	2,122	-56.6%	-57.0%
	Aprovel®/CoAprovel®	Hypertension	1,291	1,327	-2.7%	-2.4%
	Eloxatin®	Colorectal cancer	1,071	427	+150.8%	+160.9%
	Multaq®	Atrial fibrillation	261	172	+51.7%	+56.4%
	Jevtana®	Prostate cancer	188	82	+129.3%	+135.4%
	Stilnox®/Ambien® /		490	819	-40.2%	-41.4%
	Myslee®	Sleep disorders				
	Allegra®	Allergic rhinitis, urticaria	580	607	-4.4%	-8.6%
	Copaxone®	Multiple sclerosis	436	513	-15.0%	-15.4%
	Tritace®	Hypertension	375	410	-8.5%	-6.3%
	Depakine®	Epilepsy	388	372	+4.3%	+5.4%
	Xatral®	Benign prostatic hypertrophy	200	296	-32.4%	-30.7%
	Actonel®	Osteoporosis, Paget s disease	167	238	-29.8%	-29.8%
	Nasacort®	Allergic rhinitis	106	189	-43.9%	-41.8%
	<b>Other products</b>		<b>5,773</b>	<b>6,064</b>	<b>-4.8%</b>	<b>-3.4%</b>
	<b>Consumer Health Care</b>		<b>2,666</b>	<b>2,217</b>	<b>+20.3%</b>	<b>+22.8%</b>
	<b>Generics</b>		<b>1,746</b>	<b>1,534</b>	<b>+13.8%</b>	<b>+16.2%</b>
	<b>Genzyme</b>		<b>2,395</b>			
	<b>Total pharmaceuticals</b>		<b>27,890</b>	<b>26,576</b>	<b>+4.9%</b>	<b>+6.7%</b>

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The following table breaks down our 2011 and 2010 net sales for the products acquired with Genzyme:

( million)	Product	Indication	2011 Reported	2010 Reported	Change on a
					constant structure basis and at constant exchange rates (%)
	Cerezyme®	Gaucher disease	441		+11.1%
	Myozyme®/Lumizyme®	Pompe disease	308		+27.4%
	Fabrazyme®	Fabry disease	109		+9.4%
	Renagel®/Renvela®	Hyperphosphatembosis	415		+10.2%
	Synvisc®	Atherothrombosis	256		+14.7%
	Other Genzyme products		866		-2.2%
	<b>Total Genzyme</b>		<b>2,395</b>		<b>+7.7%</b>

The following table breaks down net sales of our Pharmaceutical business products by geographical region in 2011:

( million)	Product	Change at		Change at		Change at		Change at	
		Western exchange constant	United exchange constant	United exchange constant	Emerging exchange constant	Emerging exchange constant	Other exchange constant	Other exchange constant	
	Europe (1)	rates	States	rates	Markets (2)	rates	countries (3)	rates	
	Lantus®	730	+6.4%	2,336	+14.6%	617	+26.0%	233	+22.3%
	Apidra®	68	0.0%	65	+11.3%	37	+8.6%	20	+58.3%
	Insuman®	103	-4.6%			29	+20.0%		
	Amaryl®	32	-23.8%	4	-33.3%	228	+8.6%	172	-21.6%
	Other products	10							
	<b>Sub-total: Diabetes</b>	<b>943</b>	<b>+4.3%</b>	<b>2,405</b>	<b>+14.4%</b>	<b>911</b>	<b>+20.1%</b>	<b>425</b>	<b>+0.5%</b>
	Lovenox®	833	+6.4%	633	-54.3%	551	+14.0%	94	+3.5%
	Plavix®	414	-35.6%	196*	-8.0%	706	+11.9%	724	+18.6%
	Taxotere®	189	-73.6%	243	-69.2%	294	-24.6%	196	-20.2%
	Aprovel®/CoAprovel®	753	-9.1%	49*	+25.6%	363	+6.7%	126	+8.6%
	Eloxatin®	38	-19.6%	806	+393.0%	162	+9.3%	65	+10.2%
	Multaq®	66	+66.7%	184	+50.8%	7	+250.0%	4	+33.3%
	Jevtana®	44		131	+65.9%	13			
	Stilnox®/Ambien®/Myslee®	53	-3.6%	82	-80.6%	65	-1.5%	290	+8.3%
	Allegra®	13	-18.8%	3	-98.6%	99	+19.3%	465	+22.2%
	Copaxone®	415	-14.1%				-100.0%	21	+11.1%
	Tritace®	170	-10.1%			181	0.0%	24	-23.3%
	Depakine®	145	-2.0%			227	+11.5%	16	-6.7%
	Xatral®	58	-12.1%	75	-49.7%	63	-7.1%	4	-20.0%
	Actonel®	54	-48.1%			78	-12.9%	35	-22.0%
	Nasacort®	25	-10.7%	54	-57.7%	23	0.0%	4	-20.0%
	<b>Other products</b>	<b>2,417</b>	<b>-8.9%</b>	<b>497</b>	<b>-19.9%</b>	<b>2,106</b>	<b>+7.4%</b>	<b>753</b>	<b>+1.4%</b>
	<b>Consumer Health Care</b>	<b>651</b>	<b>+3.2%</b>	<b>549</b>	<b>+80.0%</b>	<b>1,225</b>	<b>+20.8%</b>	<b>241</b>	<b>+5.1%</b>
	<b>Generics</b>	<b>443</b>	<b>+9.4%</b>	<b>177</b>	<b>+79.4%</b>	<b>1,092</b>	<b>+14.0%</b>	<b>34</b>	<b>-20.0%</b>
	<b>Genzyme</b>	<b>621</b>		<b>1,180</b>		<b>347</b>		<b>247</b>	
	<b>Total pharmaceuticals</b>	<b>8,345</b>	<b>-3.9%</b>	<b>7,264</b>	<b>+8.5%</b>	<b>8,513</b>	<b>+15.0%</b>	<b>3,768</b>	<b>+14.0%</b>

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- <sup>(1)</sup> *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.*
- <sup>(2)</sup> *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*
- <sup>(3)</sup> *Japan, Canada, Australia and New Zealand.*
- \* *Sales of active ingredient to the entity majority-owned by BMS in the United States.*

**Table of Contents***Net Sales Human Vaccines (Vaccines)*

In 2011, the Vaccines segment reported net sales of 3,469 million, an 8.9% drop on a reported basis, and 5.5% at constant exchange rates. The business suffered in 2011 from the absence of sales of A/H1N1 pandemic influenza vaccines (452 million in 2010). If we exclude these sales, growth for the Vaccines business reached 7.2% at constant exchange rates, driven primarily by Emerging Markets (up 10.7%).

The drop in vaccines sales in 2011 in Western Europe (down 18.4% at constant exchange rates) and in Emerging Markets (down 18.1% at constant exchange rates) was primarily due to the lack of sales of pandemic influenza vaccines. Strong growth in the Other Countries region (up 24.2% at constant exchange rates) was driven by sales of Polio/Pertussis/Hib Vaccines in Japan.

**Polio/Pertussis/Hib** vaccines net sales were up 12.0% (at constant exchange rates) to 1,075 million, based on the solid performance of Pentaxim® (up 30.2% at constant exchange rates to 238 million) related to product launches in Russia, India and China, and of *Haemophilus influenzae type b* (Hib) vaccines (up 20.7% at 178 million) primarily in Emerging Markets and Japan.

Net sales of **influenza** in 2011 were down 33.2% at constant exchange rates to 826 million, tied to the 2011 lack of sales of pandemic influenza vaccines achieved in 2010 primarily in Latin America and Western Europe. Sales of seasonal influenza vaccines were up 2.5% at constant exchange rates, supported by the performance of Latin America.

**Meningitis/Pneumonia** vaccines generated net sales of 510 million, up 2.3% at constant exchange rates. The increase was limited by the temporary reduction in catch-up immunization programs for the Menactra® quadrivalent vaccine against meningococcal meningitis in the United States during the first half of 2011, however supported by booster vaccinations at the end of the year.

Net sales of **Adult booster** vaccines reached 465 million (up 7.3% at constant exchange rates), driven by Adacel® (314 million, up 9.2% at constant exchange rates).

Net sales of **Travel and other endemics** Vaccines fell by 1.6% at constant exchange rates to 370 million.

The following table presents the 2011 and 2010 sales of our Vaccines business by range of products:

	2011	2010	Change on a reported	Change at constant exchange
( million)	Reported	Reported	basis (%)	rates (%)
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim®)	1,075	984	+9.3 %	+12.0 %

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Influenza Vaccines (including Vaxigrip® and Fluzone®)	826	1,297	-36.3 %	-33.2 %
of which seasonal influenza vaccines	826	845	-2.2 %	+2.5 %
of which pandemic influenza vaccines		452	-100.0 %	-100.0 %
Meningitis/Pneumonia Vaccines (including Menactra®)	510	527	-3.2 %	+2.3 %
Adult Booster Vaccines (including Adacel®)	465	449	+3.6 %	+7.3 %
Travel and Other Endemics Vaccines	370	382	-3.1 %	-1.6 %
Other Vaccines	223	169	+32.0 %	+37.8 %
<b>Total Vaccines</b>	<b>3,469</b>	<b>3,808</b>	<b>-8.9%</b>	<b>-5.5%</b>

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The following table presents the 2011 sales of our Vaccines business by range of products and by region:

( million)	Change at		Change at		Change at		Change at	
	Western	constant	United	constant	Emerging	constant	Other	constant
	Europe <sup>(1)</sup>	exchange	States	exchange	Markets <sup>(2)</sup>	exchange	countries <sup>(3)</sup>	exchange
	Reported	rates	Reported	rates	Reported	rates	Reported	rates
Polio/Pertussis.Hib Vaccines								
(inc. Pentacel <sup>®</sup> and Pentaxim <sup>®</sup> )	36	-41.0 %	463	+2.8%	457	+21.9%	119	+66.7%
Influenza Vaccines <sup>(4)</sup>								
(inc. Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	77	-39.8 %	435	-11.2%	296	-51.1%	18	-21.7%
Meningitis/Pneumonia Vaccines								
(inc. Menactra <sup>®</sup> )	3	-40.0 %	390	+2.7%	104	+4.0%	13	-6.6%
Adult Booster Vaccines								
(inc. Adacel <sup>®</sup> )	76	+40.7 %	339	+3.5%	30	-9.1%	20	+11.8%
Travel and Other Endemics Vaccines	24	+33.3 %	89	+17.5%	210	-9.4%	47	-8.2%
Other Vaccines	15	-12.5 %	176	+45.3%	16	+13.3%	16	+58.7%
<b>Total Vaccines</b>	<b>231</b>	<b>-18.4 %</b>	<b>1,892</b>	<b>+2.5%</b>	<b>1,113</b>	<b>-18.1%</b>	<b>233</b>	<b>+24.2%</b>

<sup>(1)</sup> France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (the joint venture between Sanofi and Merck & Co., Inc.) are not consolidated.

<sup>(2)</sup> World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

<sup>(3)</sup> Japan, Canada, Australia and New Zealand.

<sup>(4)</sup> Seasonal and pandemic influenza vaccines.

In addition to the Vaccines activity reflected in our consolidated net sales, sales of Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, amounted to 791 million in 2011, down 13.8% on a reported basis. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. The decrease in 2011 reflects the drop in sales of Gardasil<sup>®</sup>, a vaccine that prevents papillomavirus infections known to cause cervical cancer (down 31.1% on a reported basis, to 181 million), and a decline in sales of influenza vaccines (down 23.7% on a reported basis, to 129 millions), primarily of seasonal influenza vaccines.

*Net Sales Animal Health*

The Animal Health business is carried out by Merial, which has been a wholly-owned subsidiary of Sanofi since September 18, 2009. On March 22, 2011 Merck and Sanofi announced that they had mutually terminated their agreement to form a new animal health joint venture and decided to maintain Merial and Intervet/Schering-Plough as two separate entities, operating independently. This decision was mainly due to the increasing complexity of implementing the proposed transaction. Merial is no longer presented separately on the consolidated balance sheet and the income statement since January 1, 2011 and net income from Merial has been reclassified and included in the income from continuing operations for all periods reported. Detailed information about the impact of Merial on the consolidated financial statements of Sanofi as of December 31, 2011 is provided in Note D.2. and Note D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

Meril generated net sales of 2,030 million in 2011, up 4.3% at constant exchange rates and 2.4% on a reported basis, led by the performance in Emerging Markets.

Net sales for the companion animals franchise were marked by moderate growth in sales of the Frontline® product range (up 0.9% at constant exchange rates, to 764 million), reflecting the temporary impact from generic Frontline® Plus competitors in the United States and the arrival of competitor products in the United States and Western Europe. Sales of vaccines showed sustained growth (7.2% at constant exchange rates), especially in Emerging Markets (up 14.2%) with the success of the Vaxxitex® vaccine.

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The following table presents the 2011 and 2010 sales of our Animal Health business by range of products:

	2011	2010	Change on a	Change at constant
( million)	Reported	Reported	reported basis	exchange rates
Frontline® and other fipronil-based products	764	774	-1.3%	+0.9%
Vaccines	662	627	+5.6%	+7.2%
Avermectin	372	355	+4.8%	+6.5%
Other products	232	227	+2.2%	+4.4%
<b>Total Animal Health</b>	<b>2,030</b>	<b>1,983</b>	<b>+2.4%</b>	<b>+4.3%</b>

The following table breaks down net sales of our Animal Health business products by geographical region in 2011:

	Change at constant		Change at constant		Change at constant		Change at constant	
( million)	Western	exchange rates	United States	exchange rates	Emerging Markets (2)	exchange rates	Other countries (3)	exchange rates
<b>Product</b>	<b>Europe (1)</b>		<b>States</b>		<b>Markets (2)</b>		<b>countries (3)</b>	
Frontline® and other fipronil-based products	206	+4.5%	411	-2.1%	86	+8.8%	61	0.0%
Vaccines	195	+2.6%	126	+2.3%	325	+14.2%	16	-21.1%
Avermectin	64	+8.5%	177	+2.8%	60	+8.9%	71	+13.6%
Other products	89	-6.4%	87	+24.3%	36	+11.8%	20	-24.0%
<b>Total Animal Health</b>	<b>554</b>	<b>+2.4%</b>	<b>801</b>	<b>+2.1%</b>	<b>507</b>	<b>+12.4%</b>	<b>168</b>	<b>-1.2%</b>

(1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2) World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

(3) Japan, Canada, Australia and New Zealand.

\* Sales of active ingredient to the entity majority-owned by BMS in the United States.

*Net Sales by Geographical Region*

We divide our sales geographically into four regions: Western Europe, the United States, Emerging Markets and other countries. The following table breaks down our 2011 and 2010 net sales by region:

	2011	2010	Change on a	Change at constant
( million)	Reported	Reported	reported basis	exchange rates



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Western Europe <sup>(1)</sup>	9,130	9,539	-4.3%	-4.0%
United States	9,957	9,790	+1.7%	+6.8%
Emerging Markets <sup>(2)</sup>	10,133	9,533	+6.3%	+10.1%
<i>Of which Eastern Europe and Turkey</i>	2,666	2,659	+0.3%	+3.7%
<i>Of which Asia (excl. Pacific region) <sup>(3)</sup></i>	2,416	2,095	+15.3%	+16.5%
<i>Of which Latin America</i>	3,111	2,963	+5.0%	+11.8%
<i>Of which Africa</i>	949	880	+7.8%	+9.7%
<i>Of which Middle East</i>	872	825	+5.7%	+8.6%
Other Countries <sup>(4)</sup>	4,169	3,505	+18.9%	+13.8%
<i>Of which Japan</i>	2,865	2,275	+25.9%	+20.2%
<b>Total</b>	<b>33,389</b>	<b>32,366</b>	<b>+3.2%</b>	<b>+5.3%</b>

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- (1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.
- (2) World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.
- (3) Japan, Australia and New Zealand.
- (4) Japan, Canada, Australia and New Zealand.

Western Europe posted a 4% decrease in net sales at constant exchange rates to 9,130 million, hit by competition from generics of Taxotere® (down 73.6% at constant exchange rates) and Plavix® (down 35.6% at constant exchange rates), the transfer of the Copaxone® business to Teva in certain countries, as well as the impact of austerity measures. Excluding A/H1N1 vaccines and Genzyme, the decline was 10.5% at constant exchange rates.

The United States posted a 6.8% increase in net sales at constant exchange rates to 9,957 million but excluding A/H1N1 vaccines and Genzyme, showed a 5.7% decline. Sales were affected by competition from generic versions of Lovenox®, Taxotere® and Ambien® CR, which were partially offset by the performance of Lantus® and Eloxatin® as well as by the successful launch of Allegra® as an over-the-counter product.

In Emerging Markets, net sales totaled 10,133 million, up 10.1% at constant exchange rates. Growth at constant exchange rates reached 10.4% excluding sales of A/H1N1 vaccines posted in 2010 (361 million, primarily in Latin America) and Genzyme. In Brazil, net sales hit 1,522 million, up 4.9% at constant exchange rates, or 21.9% if we exclude A/H1N1 vaccines, thereby reflecting the solid performance of generics and the contribution made by Genzyme. In China, net sales totaled 981 million (up 40.4% at constant exchange rates), supported by the performance of Plavix® and Lantus®. In Eastern Europe and Turkey, growth (3.7% at constant exchange rates) suffered from lower prices and competition from Taxotere® generics in Turkey; Russia posted sales of 732 million, a growth of 11.2% at constant exchange rates.

In the Other Countries region, net sales totaled 4,169 million, up 13.8% at constant exchange rates. Excluding A/H1N1 vaccines and Genzyme, net sales increased by 6.2%. Japan recorded net sales of 2,865 million (up 20.2% at constant exchange rates), buoyed by the solid performance of Plavix® (up 22.9% to 671 million), Allegra® (up 22.2% to 465 million) and Hib vaccines, as well as the contribution from Genzyme.

*Worldwide Presence of Plavix® and Aprovel®*

Two of our leading products Plavix® and Aprovel® were discovered by Sanofi and jointly developed with Bristol-Myers Squibb (BMS) under an alliance agreement. In all territories except Japan, these products are sold either by Sanofi or by BMS in accordance with the terms of this alliance agreement which is described in Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb above.

Worldwide sales of these two products are an important indicator because they facilitate a financial statement user's understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitate a user's ability to understand and assess the effectiveness of our research and development efforts.

Also, disclosing sales made by BMS of these two products enables the users to have a clearer understanding of trends in different lines of our income statement, in particular the lines Other revenues, where we record royalties received on those sales (see Other Revenues); Share of profit/loss of associates and joint ventures (see Share of Profit/Loss of Associates and Joint Ventures), where we record our share of profit/loss of entities included in the BMS Alliance and under BMS operational management; and Net income attributable to non-controlling interests (see Net Income Attributable to Non-Controlling Interests), where we record the BMS share of profit/loss of entities included in the BMS Alliance and under our operational management.



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The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2011 and 2010, by geographic region:

( million)	2011			2010			Change at	
	Sanofi (2)	BMS (3)	Total	Sanofi (2)	BMS (3)	Total	Change on a reported basis	constant exchange rates
<b>Plavix®/Iscover® (1)</b>								
Europe	530	44	574	724	98	822	-30.2%	-29.8%
United States		4,759	4,759		4,626	4,626	+2.9%	+7.8%
Other countries	1,370	286	1,656	1,165	282	1,447	+14.4%	+13.8%
<b>Total</b>	<b>1,900</b>	<b>5,089</b>	<b>6,989</b>	<b>1,889</b>	<b>5,006</b>	<b>6,895</b>	<b>+1.4%</b>	<b>+4.5%</b>
<b>Aprovel®/Avapro®</b>								
<b>/Karvea®/Avalide® (4)</b>								
Europe	694	130	824	789	158	947	-13.0%	-13.0%
United States		374	374		482	482	-22.4%	-18.8%
Other countries	451	156	607	411	216	627	-3.2%	-2.1%
<b>Total</b>	<b>1,145</b>	<b>660</b>	<b>1,805</b>	<b>1,200</b>	<b>856</b>	<b>2,056</b>	<b>-12.2%</b>	<b>-11.0%</b>

(1) Plavix® is marketed under the trademarks Plavix® and Iscover®.

(2) Net sales of Plavix® consolidated by Sanofi, excluding sales to BMS ( 208 million in 2011 and 273 million in 2010). Net sales of Aprovel® consolidated by Sanofi, excluding sales to BMS ( 150 million in 2011 and 129 million in 2010).

(3) Translated into euros by Sanofi using the method described in Note B.2. Foreign currency translation to our consolidated financial statements included at Item 18 in this annual report.

(4) Aprovel® is marketed under the trademarks Aprovel®, Avapro®, Karvea® and Avalide®.

Worldwide sales of Plavix®/Iscover® totaled 6,989 million in 2011, up 4.5 % at constant exchange rates. Sales in the U.S. (consolidated by BMS) were up a sustained 7.8% at constant exchange rates, to 4,759 million. In Japan and China, Plavix® realized continued success with sales of 671 million (+22.9% at constant exchange rates) and 277 million (+27.7% at constant exchange rates) respectively. These results sharply offset the decline of Plavix® in Europe caused by competition from generics (down 29.8% at constant exchange rates, to 574 million).

Worldwide sales of Aprovel®/Avapro®/Karvea®/Avalide® totaled 1,805 million in 2011, down 11.0% at constant exchange rates, with the impact of increasing penetration of generic losartan on the market for anti-hypertensives.

**Other Revenues**

Other revenues, made up primarily of royalty income under licensing agreements contracted in connection with ongoing operations, remained stable at 1,669 million in 2011 and 2010.

Revenues from licensing under the worldwide alliance with BMS on Plavix® and Aprovel® represented 1,275 million in 2011 versus 1,303 million in 2010 (down 2.1% on a reported basis). These licensing revenues suffered the effect of the U.S. dollar depreciation against the

euro, despite the increase in Plavix<sup>®</sup> sales in the United States (up 7.8% at constant exchange rates).

*Gross Profit*

Gross profit for the year ended December 31, 2011 came to 24,156 million (72.3% of net sales), 2.0% down on the 2010 figure of 24,638 million (76.1% of net sales), and a decline of 3.8 points in the gross profit reported under sales.

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The gross margin ratio of the Pharmaceuticals segment was down 2.8 points to 75.8%, reflecting both the decrease in royalty income (-0.3 point) and the unfavorable trend in the cost of sales to net sales ratio (-2.5 points). The latter was primarily due to the unfavorable impact of new generics (especially Lovenox<sup>®</sup>, Ambien<sup>®</sup> CR and Taxotere<sup>®</sup> in the United States, and Plavix<sup>®</sup> and Taxotere<sup>®</sup> in Europe).

The gross margin ratio of the Vaccines segment was down 4.5 points to 60.2%. This change was principally due to the absence of 2011 profits from pandemic influenza vaccines, which had trended favorably in 2010.

The gross margin ratio of the Animal Health segment was down 1.0 point to 68.9%.

The Group's consolidated gross profit was also impacted in 2011 by a 476 million expense (or 1.4 points) arising from the workdown of inventories remeasured at fair value in connection with acquisitions, principally Genzyme (473 million). In 2010, this expense represented 142 million (0.4 point) and for the most part affected the workdown of Merial's inventories.

### *Research and Development Expenses*

Research and development (R&D) expenses totaled 4,811 million in 2011 (14.4% of net sales), up 5.8% on the 2010 figure of 4,547 million (14.0% of net sales).

In the Pharmaceuticals segment, R&D expenses rose by 217 million or an increase of 5.6%. Excluding Genzyme, R&D expenses decreased by 4.3% at constant exchange rates as a result of reorganizations initiated in 2009, and of the streamlining of the project portfolio.

In the Vaccines segment, R&D expenses rose by 47 million year-on-year (to 564 million) or an increase of 9.1%, due mainly to the clinical trials of vaccines against dengue fever and Clostridium difficile.

In the Animal Health segment, R&D expenses declined by 9 million year-on-year or a decrease of 5.8%.

### *Selling and General Expenses*

Selling and general expenses amounted to 8,536 million (25.6% of net sales), an increase of 4.7% on the prior-year figure of 8,149 million (25.2% of net sales).

The Pharmaceuticals segment generated a 414 million increase, or 5.9%, primarily from the consolidation of Genzyme. Excluding Genzyme, selling and general expenses dropped by 2.9% at constant exchange rates, due both to reduced costs for genericized products in Europe and the

United States and tight control of general expenses.

In the Vaccines segment, selling and general expenses were down 61 million or 10.1% due to the decline in selling expenses for pandemic influenza vaccines.

In the Animal Health business, selling and general expenses were up 13 million (+2.2%), in line with the increase in net sales.

*Other Operating Income and Expenses*

Other operating income totaled 319 million in 2011 (versus 369 million in 2010), and other operating expenses accounted for 315 million (compared with 292 million in 2010).

The balance of other operating income and expenses represented a net profit of 4 million in 2011, compared with 77 million in 2010. The year-on-year decrease of 73 million was essentially due to the discontinuation of royalty payments from Teva on North American sales of Copaxone® from the second quarter of 2010.

This line item also includes expenses for the 2011 acquisition of Genzyme ( 65 million), as well as a net operational foreign exchange loss of 5 million compared to 138 million in 2010: the latter occurred in the middle of a highly volatile exchange environment.

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### *Amortization of Intangible Assets*

Amortization charged against intangible assets in the year ended December 31, 2011 amounted to 3,314 million, compared with 3,529 million in the previous year. The decline of 215 million was mainly due to a drop in amortization charged against intangible assets recognized on the acquisition of Aventis ( 1,788 million in 2011, versus 3,070 million in 2010, as products have reached the end of their life cycles and faced competition from generics), that was partly compensated by new amortization charges in 2011 generated by intangible assets recognized on the acquisition of Genzyme in the second quarter of 2011 and on the consolidation of Merial in the first quarter of 2011 ( 709 million and 353 million, respectively).

### *Impairment of Intangible Assets*

This line recorded net impairment losses against intangible assets of 142 million in 2011, compared with 433 million in 2010. Impairment losses booked in 2011 were mainly associated with (i) discontinuing a Genzyme research project, (ii) Zentiva generics for which the sales outlook was adjusted downward, and (iii) discontinuing a project developed jointly with Metabolex in the field of diabetes. It also includes an impairment reversal in connection with Actonel<sup>®</sup>, pursuant to confirmation of the terms of the collaboration agreement with Warner Chilcott (see Note C.2. to the consolidated financial statements included at Item 18 of this annual report).

In 2010, impairments were primarily related to (i) Actonel<sup>®</sup> due to planned changes to the terms of the collaboration agreement with Warner Chilcott; (ii) the pentavalent vaccine Shan5<sup>®</sup>, for which sales projections had been revised to factor in the need for another WHO pre-qualification following a flocculation problem encountered in some batches; (iii) the BSI-201 project in which the development plan was revised following the announcement of the initial Phase III trial results in metastatic triple negative breast cancer; and (iv) certain generics and Zentiva consumer health products for which sales projections in Eastern Europe were revised downwards.

### *Fair Value Remeasurement of Contingent Consideration Liabilities*

This line item records fair value remeasurements of liabilities related to business combinations accounted for in accordance with IFRS 3R. Such remeasurements generated a new profit of 15 million in 2011, and were mainly related to a contingent purchase consideration on the acquisition of TargeGen, the contingent value rights (CVRs) issued as part of the Genzyme acquisition, and the contingent consideration to be paid to Bayer on certain Genzyme products (see Note D.18. to the consolidated financial statements included at Item 18 of this annual report).

### *Restructuring Costs*

Restructuring costs accounted for a 1,314 million expense in 2011, compared with 1,384 million in 2010.

In 2011, these were mainly employee-related expenses incurred under plans to adjust headcount in support functions and sales forces in Europe, and in Research & Development in Europe and the United States, and measures to adapt the Group's manufacturing facilities in Europe.



In 2010, these costs related mainly to measures taken to adapt our industrial operations in France, and our sales and R&D functions in the United States and some European countries.

*Other Gains and Losses, and Litigation*

This line item included a net expense of \$327 million, which mainly represented (i) a backlog of depreciation and amortization expense against Meril's tangible and intangible assets in the amount of \$519 million, that had not been recognized from September 18, 2009 through December 31, 2010 because these assets had been classified as held for sale or exchange in accordance with IFRS 5 (see Note D.8.1. to the consolidated financial statements included at Item 18 of this annual report), (ii) proceeds of \$210 million in damages with regard to a Plavi<sup>®</sup> patent and (iii) the impact of the disposal of the Dermik dermatology business (see Note D.28. to the consolidated financial statements).

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In 2010, this line item reported a 138 million expense for adjustment of warranty provisions associated with prior disposals of operations.

### *Operating Income*

Operating income totaled 5,731 million for 2011, versus 6,535 million for 2010, down 12.3% mainly as a result of the competition from generics and the absence of A/H1N1 pandemic influenza vaccine sales in 2011.

### *Financial Income and Expenses*

Net financial expenses came to 412 million in 2011 versus 362 million in 2010, an increase of 50 million.

Financial expenses directly related to net debt (defined as short-term and long-term debt, plus related interest rate and currency derivatives, minus cash and cash equivalents) were 325 million in 2011 versus 324 million in 2010. This stabilization was a result of:

a drop in the average interest rate due to the sharply lower rate on the debt to fund the acquisition of Genzyme in the first quarter of 2011, which, despite the spike in average debt, generated a slight increase in the interest expense;

a rise in the Group's financial income due to the increase in average level of cash the Group held during the year and a higher average rate of return.

Provisions against securities and receivables totaled 58 million in 2011 (versus 6 million in 2010); in 2011, these provisions were primarily related to the impairment of Greek bonds.

Gains on disposals of non-current financial assets came to 25 million versus 61 million in 2010. These were essentially related to the 2011 change in the consolidation method for Yves Rocher securities associated with the loss of significant influence (see Note D.6. to the consolidated financial statements), and the Group's 2010 sale of its equity interest in Novexel.

Lastly, net financial foreign exchange gains totaled 10 million in 2011 (versus a net loss of 20 million in 2010).

### *Income before Tax and Associates and Joint Ventures*

Income before tax and associates and joint ventures was 5,319 million in 2011, versus 6,173 million in 2010, a decrease of 13.9%.

*Income Tax Expense*

Income tax expense totaled 455 million in 2011, compared with 1,430 million in 2010. The decrease was mainly due to the change in deferred taxes following changes in both the rate and the laws (mainly in the UK), and the effect of the Franco-American Advance Pricing Agreements (APA) for the 2006-2011 period (see Note D.30. to the consolidated financial statements).

This line item also includes the tax effects of the amortization of intangible assets ( 1,178 million in 2011 versus 1,183 million in 2010) and of restructuring costs ( 399 million in 2011 versus 466 million in 2010).

The effective tax rate is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. The effective tax rate was 27.0% in 2011, versus 27.8% in 2010. The difference relative to the corporate income tax rate applicable in France (34.4%) was mainly due to lower taxes on patent royalties in France.

**Table of Contents***Share of Profit/Loss of Associates and Joint Ventures*

Our share of profits and losses from associates and joint ventures totaled 1,070 million in 2011, compared with 978 million in 2010. This line mainly includes our share of after-tax profits generated in territories managed by BMS under the Plavix® and Avapro® alliance, which advanced by 9.2% to 1,070 million compared with 980 million in 2010. The increase in 2011 in this share was partly related to growth in Plavixales in the United States (up 2.9%).

*Net Income*

Net income for the year was 5,934 million in 2011, compared with 5,721 million in 2010.

*Net Income Attributable to Non-Controlling Interests*

Net income attributable to non-controlling interests amounted to 241 million in 2011, compared with 254 million in 2010. This line mainly includes the share of pre-tax profits paid to BMS generated in territories managed by Sanofi (225 million, versus 238 million in 2010); this decline is directly related to increased competition from clopidogrel (Plavix®) generics in Europe.

*Net Income Attributable to Equity Holders of Sanofi*

Net income attributable to equity holders of Sanofi totaled 5,693 million in 2011, against 5,467 million in 2010.

Basic earnings per share for 2011 was 4.31, 2.9% higher than the 2010 figure of 4.19, based on an average number of shares outstanding of 1,321.7 million in 2011 compared with 1,305.3 million in 2010. Diluted earnings per share was 4.29 in 2011 compared with 4.18 in 2010, based on an average number of shares outstanding after dilution of 1,326.7 million in 2011 and 1,308.2 million in 2010.

*Business Operating Income*

Business operating income for 2011 was 12,144 million, compared to 12,863 million in 2010. The table below shows trends in business operating income by business segment for 2011 and 2010:

<i>( million)</i>	<b>2011</b>	<b>2010</b>
Pharmaceuticals	10,496	10,965

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Vaccines	985	1,379
Animal Health	627	621
Other	36	(102)
<b>Business operating income</b>	<b>12,144</b>	<b>12,863</b>

*Business Net Income*

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance (see Item 5. Operating and Financial Review and Prospects - Business Net Income - above).

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Business net income totaled 8,795 million in 2011 versus 9,215 million in 2010, a drop of 4.6%. It represented 26.3% of net sales compared with 28.5% in 2010.

<i>( million)</i>	<b>2011</b>	<b>2010 <sup>(1)</sup></b>
<b>Business net income</b>	<b>8,795</b>	<b>9,215</b>
(i) Amortization of intangible assets	(3,314)	(3,529)
(ii) Impairment of intangible assets	(142)	(433)
(iii) Fair value remeasurement of contingent consideration liabilities	15	
(iv) Expenses arising from the impact of acquisitions on inventories <sup>(2)</sup>	(476)	(142)
(v) Restructuring costs	(1,314)	(1,384)
(vi) Other gains and losses, and litigation <sup>(3)</sup>	(327)	(138)
(vii) Impact of the non-depreciation of the property, plant and equipment of Merial (IFRS 5)		77
(viii) Tax effects on the items listed above, comprising:	<i>1,905</i>	<i>1,856</i>
<i>amortization of intangible assets</i>	<i>1,178</i>	<i>1,183</i>
<i>impairment of intangible assets</i>	<i>37</i>	<i>143</i>
<i>fair value remeasurement of contingent consideration liabilities</i>	<i>34</i>	
<i>expenses arising from the impact of acquisitions on inventories</i>	<i>143</i>	<i>44</i>
<i>restructuring costs</i>	<i>399</i>	<i>466</i>
<i>other gains and losses, and litigation</i>	<i>114</i>	<i>46</i>
<i>non-depreciation of property, plant and equipment of Merial (IFRS 5)</i>		<i>(26)</i>
(iv)/(ix) Other tax items <sup>(4)</sup>	577	
(x) Share of items listed above attributable to non-controlling interests	6	3
(iv)/(v) Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures <sup>(5)</sup>	(32)	(58)
<b>Net income attributable to equity holders of Sanofi</b>	<b>5,693</b>	<b>5,467</b>

<sup>(1)</sup> The results of operations of Merial, which was previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough will be maintained as two separate businesses operating independently (see Notes D.2. and D.8.1. to our consolidated financial statements included at Item 18 of this annual report).

<sup>(2)</sup> This line comprises the workdown of inventories remeasured at fair value at the acquisition date.

<sup>(3)</sup> See Note D.28. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(4)</sup> In 2011, related to Advance Pricing Agreement impact for 349 million and 228 million reflecting a decrease in deferred tax liabilities related to the remeasurement of intangible assets following changes in tax laws.

<sup>(5)</sup> This line shows the portion of major restructuring costs incurred by associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill).

**Business Earnings Per Share**

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see Business Net Income above).

Business earnings per share for 2011 were 6.65 versus 7.06 in 2010, down 5.8% based on a weighted average number of shares outstanding of 1,321.7 million in 2011 compared with 1,305.3 million in 2010. Diluted business earnings per share for 2011 were 6.63 versus 7.04 in 2010, down 5.8% based on a weighted average number of shares outstanding of 1,326.7 million in 2011 and 1,308.2 million in 2010.

**Table of Contents****Year Ended December 31, 2010 Compared with Year Ended December 31, 2009**

The consolidated income statements for the years ended December 31, 2010 and December 31, 2009 break down as follows:

(under IFRS)		as % of		as % of
( million)	2010 <sup>(1)</sup>	net sales	2009	net sales
<b>Net sales</b>	<b>32,367</b>	<b>100.0%</b>	<b>29,785</b>	<b>100.0%</b>
Other revenues	1,669	5.2%	1,447	4.9%
Cost of sales	(9,398)	(29.0%)	(8,107)	(27.2%)
<b>Gross profit</b>	<b>24,638</b>	<b>76.1%</b>	<b>23,125</b>	<b>77.6%</b>
Research & development expenses	(4,547)	(14.0%)	(4,626)	(15.5%)
Selling & general expenses	(8,149)	(25.2%)	(7,464)	(25.1%)
Other operating income	369		861	
Other operating expenses	(292)		(481)	
Amortization of intangible assets	(3,529)		(3,528)	
Impairment of intangible assets	(433)		(372)	
Fair value remeasurement of contingent consideration liabilities				
Restructuring costs	(1,384)		(1,080)	
Other gains and losses, and litigation <sup>(2)</sup>	(138)			
<b>Operating income</b>	<b>6,535</b>	<b>20.2%</b>	<b>6,435</b>	<b>21.6%</b>
Financial expenses	(468)		(325)	
Financial income	106		27	
<b>Income before tax and associates and joint ventures</b>	<b>6,173</b>	<b>19.1%</b>	<b>6,137</b>	<b>20.6%</b>
Income tax expense	(1,430)		(1,399)	
Share of profit/(loss) of associates and joint ventures	978		953	
<b>Net income</b>	<b>5,721</b>	<b>17.7%</b>	<b>5,691</b>	<b>19.1%</b>
Net income attributable to non-controlling interests	254		426	
<b>Net income attributable to equity holders of Sanofi</b>	<b>5,467</b>	<b>16.9%</b>	<b>5,265</b>	<b>17.7%</b>
Average number of shares outstanding (million)	1,305.3		1,305.9	
Average number of shares outstanding after dilution (million)	1,308.2		1,307.4	
Basic earnings per share (in euros)	4.19		4.03	
Diluted earnings per share (in euros)	4.18		4.03	

<sup>(1)</sup> The results of operations of Meril, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with IFRS 5.36., following the announcement that Meril and Intervet/Schering-Plough will be maintained as separate businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).

<sup>(2)</sup> See Note B.20.2. to our consolidated financial statements included at Item 18 of this annual report.

**Net Sales**

Net sales for the year ended December 31, 2010 were 32,367 million, up 8.7% on 2009. Growth was sustained by both the appreciation of the U.S. dollar and the yen against the euro, and changes in structure (mainly the consolidation of Zentiva from the second quarter of 2009, of Meril from September 18, 2009, and of Chattem from the first quarter of 2010).

Our net sales comprise the net sales generated by our Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health businesses.





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The following table breaks down our 2010 and 2009 net sales by business segment:

	2010	2009	Change on a reported basis
( million)	Reported	Reported	(%)
Pharmaceuticals	26,576	25,823	+2.9%
Vaccines	3,808	3,483	+9.3%
Animal Health	1,983	479	+314.0%
<b>Total</b>	<b>32,367</b>	<b>29,785</b>	<b>+8.7%</b>

*Net Sales by Product - Pharmaceuticals*

Net sales generated by our Pharmaceuticals segment were 26,576 million in 2010, up 2.9% on a reported basis but down 1.6% at constant exchange rates.

*Flagship Products*

Our flagship products (Lantus<sup>®</sup> and other Diabetes business products, Lovenox<sup>®</sup>, Plavix<sup>®</sup>, Taxotere<sup>®</sup>, Aprovel<sup>®</sup>/CoAprovel<sup>®</sup>, Eloxatin<sup>®</sup>, Multaq<sup>®</sup> and Jevtana<sup>®</sup>) are discussed below. Sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> are discussed further below under Worldwide Presence of Plavix<sup>®</sup> and Aprovel<sup>®</sup>.

Net sales for the Diabetes business came to 4,298 million, up 9.2% at constant exchange rates, driven by growth for Lantus<sup>®</sup>, Apidra<sup>®</sup> and Amaryl<sup>®</sup>.

**Lantus<sup>®</sup>**, the world's leading diabetes brand (source: IMS 2011 sales), posted a 9.1% rise in net sales at constant exchange rates in 2010 to 3,510 million. Growth was strong in Emerging Markets (18.2% at constant exchange rates), but slowed in the United States (7.4% at constant exchange rates) due to healthcare reforms, despite higher sales of the SoloSTAR<sup>®</sup> injection pen. Lantus<sup>®</sup> achieved particularly strong growth at constant exchange rates in Japan (32.3%), Russia (25.9%), and Brazil (30.6%).

Net sales of the rapid-acting insulin analog **Apidra<sup>®</sup>** advanced by 24.1% at constant exchange rates in 2010 to 177 million, buoyed by solid performances in Western Europe (21.8% growth) and Emerging Markets (37.5% growth).

**Lovenox<sup>®</sup>** saw net sales decrease by 10.5% at constant exchange rates in 2010 to 2,806 million. In the United States, sales fell by 22.7% to 1,439 million following the introduction of a generic version of enoxaparin at the end of July 2010. Excluding the United States, net sales were up 7.8% at constant exchange rates at 1,367 million (representing 48.7% of worldwide 2010 sales of Lovenox<sup>®</sup>), with good performances in Western Europe (up 7.3%) and Eastern Europe (up 14.0%).

**Taxotere**<sup>®</sup> reported net sales of 2,122 million, down 6.4% at constant exchange rates. The drop in sales came in the United States and Western Europe, where the patents expired in November 2010. Generic docetaxel became available throughout Western Europe by November 2010. In the United States, distributors commenced a work down of Taxotere<sup>®</sup> inventories in late 2010 in anticipation of the expected arrival of generic docetaxel in 2011. However, the product saw modest growth in Emerging Markets and in the Other Countries region (1.4% and 2.5% respectively).

Net sales of **Eloxatin**<sup>®</sup> fell by 58.8% at constant exchange rates in 2010 to 427 million, hit by competition from generics. Following a court ruling, generics manufacturers have been under order to stop selling their unauthorized Eloxatin<sup>®</sup> generics in the U.S. market since June 30, 2010. The workdown of existing inventories of generics impaired our Eloxatin<sup>®</sup> sales performance in the second half of 2010.

**Multaq**<sup>®</sup>, which began to be marketed at the end of 2009, reported net sales of 172 million, mainly in the United States. The product is now available in over 20 countries, and further launches are ongoing.

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**Jevtana**<sup>®</sup>, which has been available in the U.S. market since July 2010, registered net sales of 82 million in 2010.

Our other major products are described below.

Net sales of the hypnotic **Stilnox**<sup>®</sup>/**Ambien**<sup>®</sup>/**Myslee**<sup>®</sup> fell by 10.9% at constant exchange rates to 819 million. In the United States, net sales were 443 million (including 375 million for **Ambien**<sup>®</sup> CR), down 21.6% at constant exchange rates, following FDA approval of a generic version of **Ambien**<sup>®</sup> CR in October 2010; we responded by launching our own generic version in the United States. In Japan, **Myslee**<sup>®</sup> again performed well, with net sales up 14.5% at constant exchange rates at 247 million.

**Allegra**<sup>®</sup> reported a 22.4% drop in net sales (at constant exchange rates) to 607 million, due to the effect of generics of **Allegra**<sup>®</sup> D-12, which have been available on the U.S. market since the end of 2009. Sales in Japan were down 2.0% at constant exchange rates, at 356 million.

Net sales of **Copaxone**<sup>®</sup>, generated mainly in Western Europe, grew by 8.4% at constant exchange rates to 513 million.

The **Consumer Health Care** business posted year-on-year growth of 45.7% at constant exchange rates to 2,217 million, driven by Emerging Markets where net sales rose by 44.4% at constant exchange rates to 1,050 million. These figures consolidate the consumer health products of Zentiva from April 2009, Oenobiol from December 2009, Chattem from February 2010, and Nepentes from August 2010.

The **Generics** business reported 2010 net sales of 1,534 million, up 41.5% at constant exchange rates. Growth was driven by Emerging Markets, due to the acquisition and consolidation of Zentiva and Kendrick (from April 2009) and Medley (from May 2009), and by the United States, following the launch of our generic version of **Ambien**<sup>®</sup> CR.

Net sales of the other products in the portfolio were down 1.9% (at constant exchange rates) year-on-year at 6,064 million. For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Pharmaceutical Products.

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The following table breaks down our 2010 and 2009 net sales for the Pharmaceuticals business by product:

( million)	Product	Indication	2010 Reported	2009 Reported	Change on	Change at
					a reported	constant
					basis (%)	exchange
					rates (%)	
	Lantus®	Diabetes	3,510	3,080	+14.0%	+9.1%
	Apidra®	Diabetes	177	137	+29.2%	+24.1%
	Amaryl®	Diabetes	478	416	+14.9%	+7.7%
	Insuman®	Diabetes	133	131	+1.5%	+1.5%
	<b>Sub-total: Diabetes</b>		<b>4,298</b>	<b>3,764</b>	<b>+14.2%</b>	<b>+9.2%</b>
	Lovenox®	Thrombosis	2,806	3,043	-7.8%	-10.5%
	Plavix®	Atherothrombosis	2,083	2,623	-20.6%	-24.6%
	Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	2,122	2,177	-2.5%	-6.4%
	Aprovel®/CoAprovel®	Hypertension	1,327	1,236	+7.4%	+4.2%
	Eloxatin®	Colorectal cancer	427	957	-55.4%	-58.8%
	Multaq®	Atrial fibrillation	172	25	+588.0%	+560.0%
	Jevtana®	Prostate cancer	82			
	Stilnox® / Ambien®/Myslee®	Sleep disorders	819	873	-6.2%	-10.9%
	Allegra®	Allergic rhinitis, urticarial	607	731	-17.0%	-22.4%
	Copaxone®	Multiple sclerosis	513	467	+9.9%	+8.4%
	Tritace®	Hypertension	410	429	-4.4%	-7.2%
	Depakine®	Epilepsy	372	329	+13.1%	+7.6%
	Xatral®	Benign prostatic hypertrophy	296	296	0.0%	-3.4%
	Actonel®	Osteoporosis, Paget s disease	238	264	-9.8%	-16.3%
	Nasacort®	Allergic rhinitis	189	220	-14.1%	-16.8%
	<b>Other products</b>		<b>6,064</b>	<b>5,947</b>	<b>+2.0%</b>	<b>-1.9%</b>
	<b>Consumer Health Care</b>		<b>2,217</b>	<b>1,430</b>	<b>+55.0%</b>	<b>+45.7%</b>
	<b>Generics</b>		<b>1,534</b>	<b>1,012</b>	<b>+51.6%</b>	<b>+41.5%</b>
	<b>Total pharmaceuticals</b>		<b>26,576</b>	<b>25,823</b>	<b>+2.9%</b>	<b>-1.6%</b>

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The following table breaks down net sales of our Pharmaceutical business products by geographical region in 2010:

( million)	Western Europe <sup>(1)</sup>	Change at	United States	Change at	Emerging Markets <sup>(2)</sup>	Change at	Other Countries <sup>(3)</sup>	Change at
		constant exchange rates		constant exchange rates		constant exchange rates		constant exchange rates
<b>Product</b>								
Lantus <sup>®</sup>	684	+5.3%	2,134	+7.4%	508	+18.2%	184	+25.2%
Apidra <sup>®</sup>	68	+21.8%	62	+11.1%	35	+37.5%	12	+150.0%
Amaryl <sup>®</sup>	42	-17.6%	6	-33.3%	222	+21.7%	208	+3.3%
Insuman <sup>®</sup>	108	-0.9%			25	+19.0%		-100.0%
<b>Sub-total: Diabetes</b>	<b>902</b>	<b>+4.2%</b>	<b>2,202</b>	<b>+7.4%</b>	<b>790</b>	<b>+20.0%</b>	<b>404</b>	<b>+13.7%</b>
Lovenox <sup>®</sup>	782	+7.3%	1,439	-22.7%	499	+6.9%	86	+19.4%
Plavix <sup>®</sup>	641	-53.9%	213*	-4.1%	648	+0.7%	581	+25.4%
Taxotere <sup>®</sup>	709	-10.6%	786	-8.0%	394	+1.4%	233	+2.5%
Aprovel <sup>®</sup> /CoAprovel <sup>®</sup>	825	-5.0%	39*	+457.1%	358	+8.3%	105	+67.3%
Eloxatin <sup>®</sup>	46	-42.9%	172	-76.4%	150	-9.8%	59	+4.0%
Multaq <sup>®</sup>	39		128		2		3	
Jevtana <sup>®</sup>			82					
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Myslee <sup>®</sup>	55	-8.3%	443	-21.6%	68	+5.0%	253	+13.6%
Allegra <sup>®</sup>	16	-5.9%	147	-53.6%	88	+17.4%	356	-3.2%
Copaxone <sup>®</sup>	482	+9.1%			13	-13.3%	18	+7.7%
Tritace <sup>®</sup>	189	-4.1%			191	-2.6%	30	-41.9%
Depakine <sup>®</sup>	148	+2.1%			209	+12.0%	15	+9.1%
Xatral <sup>®</sup>	66	-14.3%	155	+2.7%	70	+0.0%	5	-50.0%
Actonel <sup>®</sup>	104	-23.5%			93	-12.4%	41	+3.2%
Nasacort <sup>®</sup>	28	-3.4%	130	-20.3%	26	-10.7%	5	-20.0%
<b>Other products</b>	<b>2,649</b>	<b>-2.3%</b>	<b>652</b>	<b>+3,3%</b>	<b>2,052</b>	<b>+0.4%</b>	<b>711</b>	<b>-10.9%</b>
<b>Consumer Health Care</b>	<b>630</b>	<b>+1.1%</b>	<b>320</b>		<b>1,050</b>	<b>+44.4%</b>	<b>217</b>	<b>+31.3%</b>
<b>Generics</b>	<b>404</b>	<b>+11.1%</b>	<b>102</b>		<b>988</b>	<b>+42.8%</b>	<b>40</b>	<b>+61.9%</b>
<b>Total pharmaceuticals</b>	<b>8,715</b>	<b>-8.5%</b>	<b>7,010</b>	<b>-7,5%</b>	<b>7,689</b>	<b>+11.9%</b>	<b>3,162</b>	<b>+6.9%</b>

(1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2) World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

(3) Japan, Canada, Australia and New Zealand.

\* Sales of active ingredient to the entity majority-owned by BMS in the United States.

*Net Sales Human Vaccines (Vaccines)*

In 2010, the Vaccines segment reported net sales of 3,808 million, up 4.8% at constant exchange rates and 9.3% on a reported basis. Growth was driven by sales of seasonal influenza vaccines ( 845 million, versus 597 million in 2009). Sales of pandemic influenza vaccines (mainly against the A/H1N1 virus) were flat; excluding their impact, growth for the Vaccines segment reached 5.5% at constant exchange rates.

Although the Vaccines segment saw net sales decrease in Western Europe and the United States (by 15.6% and 11.5% at constant exchange rates, respectively), the effect was amply offset by strong growth in Emerging Markets and in the Other Countries region (of 46.2% and 23.0% at constant exchange rates, respectively).



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Net sales of **influenza** vaccines rose by 18.7% at constant exchange rates to 1,297 million in 2010, boosted by the performance of the Fluzone® seasonal influenza vaccine in the U.S. market. Excluding pandemic influenza vaccines (net sales of 452 million, flat year-on-year), growth reached 33.3% at constant exchange rates.

**Polio/Pertussis/Hib** vaccines net sales fell by 2.9% (at constant exchange rates) to 984 million, reflecting a decline in sales of Pentacel® (down 11.4% at 317 million at constant exchange rates) but also the performance of Pentaxim® (up 43.9% at 190 million at constant exchange rates).

**Meningitis/Pneumonia** vaccines generated net sales of 527 million, down 6.7% at constant exchange rates, mainly due to a reduction in catch-up vaccination programs with the Menactra® quadrivalent meningococcal meningitis vaccine in the United States.

Net sales of **Adult booster** vaccines reached 449 million (up 4.7% at constant exchange rates), driven by Adacel® (301 million, up 6.1% at constant exchange rates).

Net sales of **Travel and other endemics** Vaccines rose by 15.7% at constant exchange rates to 382 million, mainly due to growth in anti-rabies vaccines.

The following table presents the 2010 and 2009 sales of our Vaccines business by range of products:

	2010	2009	Change on a reported	Change at constant exchange
( million)	Reported	Reported	basis (%)	rates (%)
Influenza Vaccines (including Vaxigrip® and Fluzone®)	1,297	1,062	+22.1%	+18.7%
of which seasonal influenza vaccines	845	597	+41.5%	+33.3%
of which pandemic influenza vaccines	452	465	-2.8%	0.0%
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim®)	984	968	+1.7%	-2.9%
Meningitis/Pneumonia Vaccines (including Menactra®)	527	538	-2.0%	-6.7%
Adult Booster Vaccines (including Adacel®)	449	406	+10.6%	+4.7%
Travel and Other Endemics Vaccines	382	313	+22.0%	+15.7%
Other Vaccines	169	196	+13.8%	-18.4%
<b>Total Vaccines</b>	<b>3,808</b>	<b>3,483</b>	<b>+9.3%</b>	<b>+4.8%</b>

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The following table presents the 2010 sales of our Vaccines business by range of products and by region:

	Change at		Change at		Change at		Change at	
	Western	constant	United	constant	Emerging	constant	Other	constant
	Europe <sup>(1)</sup>	exchange	States	exchange	Markets <sup>(2)</sup>	exchange	Countries <sup>(3)</sup>	exchange
( million)	Reported	rates	Reported	rates	Reported	rates	Reported	rates
Influenza Vaccines <sup>(4)</sup>								
(inc. Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	128	-7.9%	528	-20.2%	618	+116.4%	23	+5.6%
Polio/Pertussis.Hib Vaccines								
(inc. Pentacel <sup>®</sup> and Pentaxim <sup>®</sup> )	61	-16.2%	470	-14.6%	384	+11.4%	69	+56.4%
Meningitis/Pneumonia Vaccines								
(inc. Menactra <sup>®</sup> )	5	-54.5%	407	-11.4%	101	+25.6%	14	0.0%
Adult Booster Vaccines								
(inc. Adacel <sup>®</sup> )	54	-3.6%	345	+5.2%	33	+32.0%	17	-20.0%
Travel and Other Endemics Vaccines	18	+20.0%	80	+11.6%	235	+15.8%	49	+21.2%
Other Vaccines	16	-63.2%	128	-10.4%	15	+0.0%	10	+22.2%
<b>Total Vaccines</b>	<b>282</b>	<b>-15.6%</b>	<b>1,958</b>	<b>-11.5%</b>	<b>1,386</b>	<b>+46.2%</b>	<b>182</b>	<b>+23.0%</b>

<sup>(1)</sup> France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (the joint venture between Sanofi and Merck & Co., Inc.) are not consolidated.

<sup>(2)</sup> World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

<sup>(3)</sup> Japan, Canada, Australia and New Zealand.

<sup>(4)</sup> Seasonal and pandemic influenza vaccines.

In addition to the Vaccines activity reflected in our consolidated net sales, sales at Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, amounted to 918 million, down 18.9% on a reported basis. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. Sales of Gardasil<sup>®</sup>, a vaccine that prevents papillomavirus infections (a cause of cervical cancer), totaled 263 million in 2010, compared with 395 million in 2009. This decrease of 33.5% was mainly due to a reduction in catch-up vaccination programs.

**Net Sales Animal Health**

The Animal Health business is carried out by Merial, which has been a wholly-owned subsidiary of Sanofi since September 18, 2009. Following the mutual termination by Sanofi and Merck of their agreement to create a new animal health joint venture, Merial's results have since been included in the results from continuing operations for all periods reported (see note D.2. to our consolidated financial statements included at Item 18 of this annual report).



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Meril generated net sales of 1,983 million in 2010, up 314.0% on a reported basis. 2009 net sales were consolidated from September 18, 2009. The following table presents the 2010 and 2009 sales of our Animal Health business by range of products:

( million)	2010	2009	Change on a Reported basis
	Reported	Reported	
Frontline® and other fipronil-based products	774	195	+296.9%
Vaccines	627	131	+378.6%
Avermectin	355	90	+294.4%
Other products	227	63	+260.3%
<b>Total Animal Health</b>	<b>1,983</b>	<b>479</b>	<b>+314.0%</b>

The following table breaks down net sales of our Animal Health business products by geographical region in 2010:

( million)	2010	Western	United	Emerging	Other
Product	Net sales	Europe <sup>(1)</sup>	States	Markets <sup>(2)</sup>	countries <sup>(3)</sup>
Frontline® and other fipronil-based products	774	198	438	80	58
Vaccines	627	191	129	288	19
Avermectin	355	59	181	56	59
Other products	227	94	74	34	25
<b>Total Animal Health</b>	<b>1,983</b>	<b>542</b>	<b>822</b>	<b>458</b>	<b>161</b>

<sup>(1)</sup> France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

<sup>(2)</sup> World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

<sup>(3)</sup> Japan, Canada, Australia and New Zealand.

*Net Sales by Geographical Region*

We divide our sales geographically into four regions: Western Europe, the United States, Emerging Markets and other countries. The following table breaks down our 2010 and 2009 net sales by region:

( million)	2010	2009	Change on a Reported basis
	Reported	Reported	
Western Europe <sup>(1)</sup>	9,539	9,938	-4.0%
United States	9,790	9,573	+2.3%
Emerging Markets <sup>(2)</sup>	9,533	7,493	+27.2%
<i>Of which Eastern Europe and Turkey</i>	2,659	2,279	+16.7%
<i>Of which Asia (excl. Pacific region) <sup>(3)</sup></i>	2,095	1,638	+27.9%
<i>Of which Latin America</i>	2,963	1,991	+48.8%
<i>Of which Africa</i>	880	782	+12.5%
<i>Of which Middle East</i>	825	658	+25.4%
Other Countries <sup>(4)</sup>	3,505	2,781	+26.0%

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<i>Of which Japan</i>	2,275	1,871	+21.6%
<b>Total</b>	<b>32,367</b>	<b>29,785</b>	<b>+8.7%</b>

(1) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.*

(2) *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*

(3) *Japan, Australia and New Zealand.*

(4) *Japan, Canada, Australia and New Zealand.*

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Western Europe saw net sales decrease by 4.0% in 2010 to 9,539 million, hit by competition from generics of Plavix® and Taxotere®, and by price pressure from the healthcare authorities.

In the United States, net sales grew by 2.3% at 9,790 million, despite the arrival of generic competition for Loveno® and Ambien® CR, the workdown of inventories of generic versions of Eloxatin® during the second half of 2010 and the effects of healthcare reform. These figures include net sales generated by Chatten from February 2010 and by Merial from September 18, 2009.

Emerging Markets net sales were 9,533 million, representing robust growth of 27.2%. This performance reflected solid organic growth and the impact of acquisitions (primarily Merial, Zentiva in Eastern Europe and Medley in Brazil). Emerging Markets accounted for 29.5% of total consolidated net sales in 2010. The main growth drivers were Latin America, Russia and China. In Latin America (primarily Brazil and Mexico), growth was fueled by sales of influenza vaccines, which virtually trebled (189% growth).

In the Other Countries region, net sales rose by 26.0% to 3,505 million. Net sales in Japan reached 2,275 million, up 21.6%, thanks largely to the success of Plavix®, the performance of the Vaccines business and the integration of Merial.

### *Worldwide Presence of Plavix® and Aprovel®*

Two of our leading products Plavix® and Aprovel® were discovered by Sanofi and jointly developed with Bristol-Myers Squibb ( BMS ) under an alliance agreement. In all territories except Japan, these products are sold either by Sanofi or by BMS in accordance with the terms of this alliance agreement which is described in Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb above.

Worldwide sales of these two products are an important indicator because they facilitate a financial statement user's understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitate a user's ability to understand and assess the effectiveness of our research and development efforts.

Also, disclosing sales made by BMS of these two products enables the users to have a clearer understanding of trends in different lines of our income statement, in particular the lines Other revenues, where we record royalties received on those sales (see Other Revenues); Share of profit/loss of associates and joint ventures (see Share of Profit/Loss of Associates and Joint Ventures), where we record our share of profit/loss of entities included in the BMS Alliance and under BMS operational management; and Net income attributable to non-controlling interests (see Net Income Attributable to Non-Controlling Interests), where we record the BMS share of profit/loss of entities included in the BMS Alliance and under our operational management.

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The table below sets forth the worldwide sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> in 2010 and 2009, by geographic region:

	2010			2009			Change at	
	Sanofi <sup>(2)</sup>	BMS <sup>(3)</sup>	Total	Sanofi <sup>(2)</sup>	BMS <sup>(3)</sup>	Total	Change on a reported basis	constant exchange rates
( million)								
<b>Plavix<sup>®</sup>/Iscover<sup>®</sup><sup>(1)</sup></b>								
Europe	724	98	822	1,443	161	1,604	-48.8%	-49.2%
United States		4,626	4,626		4,026	4,026	+14.9%	+10.8%
Other countries	1,165	282	1,447	897	255	1,152	+25.6%	+13.7%
<b>Total</b>	<b>1,889</b>	<b>5,006</b>	<b>6,895</b>	<b>2,340</b>	<b>4,442</b>	<b>6,782</b>	<b>+1.7%</b>	<b>-2.9%</b>
<b>Aprovel<sup>®</sup>/Avapro<sup>®</sup></b>								
<b>/Karvea<sup>®</sup>/Avalide<sup>®</sup><sup>(4)</sup></b>								
Europe	789	158	947	810	172	982	-3.6%	-4.4%
United States		482	482		524	524	-8.0%	-10.4%
Other countries	411	216	627	314	192	506	+23.9%	+13.5%
<b>Total</b>	<b>1,200</b>	<b>856</b>	<b>2,056</b>	<b>1,124</b>	<b>888</b>	<b>2,012</b>	<b>+2.2%</b>	<b>-1.5%</b>

(1) Plavix<sup>®</sup> is marketed under the trademarks Plavix<sup>®</sup> and Iscover<sup>®</sup>.

(2) Net sales of Plavix<sup>®</sup> consolidated by Sanofi, excluding sales to BMS ( 273 million in 2010 and 311 million in 2009). Net sales of Aprovel<sup>®</sup> consolidated by Sanofi, excluding sales to BMS ( 129 million in 2010 and 113 million in 2009).

(3) Translated into euros by Sanofi using the method described in Note B.2. Foreign currency translation to our consolidated financial statements included at Item 18 in this annual report.

(4) Aprovel<sup>®</sup> is marketed under the trademarks Aprovel<sup>®</sup>, Avapro<sup>®</sup>, Karvea<sup>®</sup> and Avalide<sup>®</sup>.

In the United States, sales of Plavix<sup>®</sup>/Iscover<sup>®</sup> (consolidated by BMS) grew by a robust 10.8% in 2010 to 4,626 million. Plavix<sup>®</sup> continued to perform well in Japan and China, where sales grew respectively by 37.1% (to 520 million) and by 36.6% (to 216 million) at constant exchange rates. These performances to some extent cushioned the effect of the decline in European sales of Plavix<sup>®</sup> (down 49.2% at constant exchange rates) caused by competition from generics.

Worldwide sales of Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Avalide<sup>®</sup> were 2,056 million in 2010, down 1.5% at constant exchange rates. The performance in the Other Countries region, lifted by sales of active ingredient to our alliance partners in Japan, partially offset the drop in sales in the United States and Europe, where net sales fell by 10.4% and 4.4% respectively at constant exchange rates. At the end of 2010, sales were impacted by a voluntary recall of certain lots of Avalide<sup>®</sup> (irbesartan-hydrochlorothiazide) by Bristol-Myers Squibb and Sanofi from the U.S., Puerto Rican, Canadian, Mexican and Argentinean markets.

*Other Revenues*

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, totaled 1,669 million in 2010, 15.3% higher than the 2009 figure of 1,447 million.

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This increase was mainly due to license revenues under the worldwide alliance with BMS on Plavix<sup>®</sup> and Aprovel<sup>®</sup>, which totaled 1,303 million in 2010 versus 1,155 million in 2009 (a 12.8% rise on a reported basis). These revenues were boosted by stronger sales of Plavix<sup>®</sup> in the United States (up 10.8% at constant exchange rates), and by favorable trends in the exchange rate of the U.S. dollar against the euro.

### *Gross Profit*

Gross profit for the year ended December 31, 2010 came to 24,638 million (76.1% of net sales), 6.5% up on the 2009 figure of 23,125 million (77.6% of net sales).

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The gross margin ratio of the Pharmaceuticals segment fell by 1.6 points, reflecting the net effect of increased royalty income (+0.6 of a point) and erosion in the ratio of cost of sales to net sales (-2.2 points). This erosion was mainly due to genericization (primarily Plavix® in Europe and Lovenox® in the United States) and higher raw material prices for heparins. Nevertheless, the 2010 gross margin ratio for the Pharmaceuticals segment remained healthy at 78.6%.

The gross margin ratio of the Vaccines segment rose by 1.9 points to 64.7%, driven by a 2.1-point improvement in the ratio of cost of sales to net sales, thanks mainly to cost efficiencies in the production of pandemic influenza vaccines.

The Animal Health segment recorded a gross margin ratio of 69.9% in 2010, up 5.8 points to 69.9% due to product mix.

Consolidated gross profit was also dented by a 142 million charge in 2010 (0.4 of a point) arising from the workdown during 2010 of inventories remeasured at fair value in connection with acquisitions (principally Merial and Chattem), against 90 million in 2009 (0.3 of a point, principally Merial).

### *Research and Development Expenses*

Research and development expenses amounted to 4,547 million in 2010 (14.0% of net sales), compared with 4,626 million in 2009 (15.5% of net sales). This represents a year-on-year reduction of 1.7% on a reported basis.

The Pharmaceuticals segment generated savings of 5.1% as a result of the reorganization initiated in 2009, which has helped reorient some in-house resources towards third-party collaborations. These savings also reflect a rationalization of R&D projects following a full, objective review of the portfolio. Research and development expenses in the Vaccines segment rose by 26 million year-on-year, an increase of 5.3%. Research and development expenses in the Animal Health segment amounted to 155 million in 2010, compared to 146 million in 2009 (for the period starting September 18, 2009).

### *Selling and General Expenses*

Selling and general expenses amounted to 8,149 million (25.2% of net sales), an increase of 9.2% on the prior-year figure of 7,464 million (25.1% of net sales), reflecting the first-time consolidation of companies acquired in 2010 (primarily Chattem) and the impact of the Jevtana® and Multaq® launches. Excluding these impacts, selling and general expenses show a decrease, which reflects the transformation program initiated in 2009, and was mainly driven by savings in marketing costs in the United States and Europe, and in general expenses.

### *Other Operating Income and Expenses*

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Other operating income amounted to 369 million in 2010 (2009: 861 million), and other operating expenses totaled 292 million (2009: 481 million). Overall, other operating income and expenses represented net income of 77 million in 2010, compared with 380 million in 2009. The year-on-year decrease of 303 million was mainly due to the discontinuation of royalty payments from Teva on North American sales of Copaxone® from the second quarter of 2010.

In addition, Sanofi recorded a net operational foreign exchange loss of 141 million due to highly volatile currency markets; this compares with a net gain of 40 million in 2009.

### *Amortization of Intangible Assets*

Amortization charged against intangible assets in the year ended December 31, 2010 amounted to 3,529 million, compared with 3,528 million in the previous year. An increase in amortization expense in North America, related to trends in the U.S. dollar/euro exchange rate and the Chattem acquisition, was offset by a reduction in Europe as some intangible assets reached the end of their useful lives.

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This line item mainly comprises amortization charged against intangible assets remeasured at fair value on the acquisitions of Aventis ( 3,070 million in 2010, versus 3,175 million in 2009) and of Zentiva ( 130 million in 2010, versus 98 million in 2009).

### *Impairment of Intangible Assets*

This line recorded impairment losses of 433 million in 2010, compared with 372 million in 2009. The losses booked in 2010 related mainly to (i) Actonel<sup>®</sup>, due to contemplated amendments to the terms of the collaboration agreement with Warner Chilcott; (ii) the pentavalent vaccine Shan5<sup>®</sup>, for which sales projections were revised to take account of the need to file a new application for WHO pre-qualification following a flocculation problem in some batches; (iii) the BSI-201 project, for which the development plan was revised following the announcement of the initial results from a Phase III trial in triple-negative metastatic breast cancer; and (iv) some of Zentiva's generics and consumer health products, whose sales projections in Eastern Europe were adjusted downwards.

The net impairment loss of 372 million recognized in 2009 related mainly to Actonel<sup>®</sup>, Benzaclin<sup>®</sup> and Nasacort<sup>®</sup>, and reflected the changing competitive environment and the approval dates of generics.

### *Restructuring Costs*

Restructuring costs amounted to 1,384 million in 2010, compared with 1,080 million in 2009.

In 2010, these costs mainly related to measures taken to adapt our industrial operations in France, and our sales and R&D functions in the United States and some European countries.

In 2009, restructuring costs mainly related to measures aimed at transforming R&D operations to encourage innovation, and adapting central support functions to streamline the organizational structure. They mainly comprised employee-related expenses, in the form of early retirement benefits and termination benefits under voluntary redundancy plans. To a lesser extent, they reflected ongoing measures to adapt our industrial facilities in Europe and adjust our sales forces.

### *Other Gains and Losses, and Litigation*

In 2010, this line item reported an expense of 138 million, relating to an adjustment to vendor's guarantee provisions in connection with past divestments.

We made no material divestments in 2010 or 2009.



*Operating Income*

Operating income for 2010 was 6,535 million, versus 6,435 million for 2009, an increase of 1.6%.

*Financial Income and Expenses*

Net financial expenses were 362 million in 2010, compared with 298 million in 2009, an increase of 21.5%.

Financial expenses directly related to net debt (defined as short-term and long-term debt, plus related interest rate and currency derivatives, minus cash and cash equivalents) were 325 million in 2010, versus 230 million in 2009. This year-on-year rise reflected the following factors:

an increase in the average interest rate (due to a longer average maturity), charged on a higher level of average consolidated debt;

a reduction in interest income, reflecting a lower average rate of return; and

the 34 million of financial expenses incurred on the acquisition credit facilities contracted in October 2010 in connection with the launch of the public tender offer for Genzyme (see Item 8.B. Significant changes ).

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Gains on disposals amounted to 61 million, mainly on the sale of the equity interest in Novoxel.

Net foreign exchange losses on financial items totaled 20 million in 2010 (2009: 67 million).

### *Income before Tax and Associates and Joint Ventures*

Income before tax and associates and joint ventures was 6,173 million in 2010, versus 6,137 million in 2009, an increase of 0.6%.

### *Income Tax Expense*

Income tax expense totaled 1,430 million in 2010, compared with 1,399 million in 2009.

The effective tax rate is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. The effective tax rate was 27.8% in 2010, versus 28.2% in 2009. The difference relative to the standard income tax rate applicable in France in 2010 and 2009 (34.4%) was mainly due to royalty income being taxed at a reduced rate in France.

This line item also includes tax effects of amortization of intangible assets ( 1,183 million in 2010, 1,130 million in 2009) and of restructuring costs ( 466 million in 2010, 360 million in 2009).

### *Share of Profit/Loss of Associates and Joint Ventures*

Our share of profits and losses from associates and joint ventures was 978 million in 2010, compared with 953 million in 2009. This line mainly includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance, which rose by 24.8% from 785 million in 2009 to 980 million in 2010. This year-on-year increase was mainly related to stronger sales of Plavix in the United States (up 10.8% at constant exchange rates) and to the appreciation of the U.S. dollar against the euro (positive impact of 3.7%).

### *Net Income*

Net income for the year was 5,721 million in 2010, compared with 5,691 million in 2009.

*Net Income Attributable to Non-Controlling Interests*

Net income attributable to non-controlling interests amounted to 254 million in 2010, compared with 426 million in 2009. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (238 million, versus 405 million in 2009). The decrease in net income attributable to non-controlling interests in 2010 was directly related to increased competition from generics of clopidogrel (Plavix®) in Europe.

*Net Income Attributable to Equity Holders of Sanofi*

Net income attributable to equity holders of Sanofi totaled 5,467 million in 2010, against 5,265 million in 2009.

Basic earnings per share for 2010 was 4.19, 4.0% higher than the 2009 figure of 4.03, based on an average number of shares outstanding of 1,305.3 million in 2010 and 1,305.9 million in 2009. Diluted earnings per share was 4.18 in 2010 compared with 4.03 in 2009, based on an average number of shares outstanding after dilution of 1,308.2 million in 2010 and 1,307.4 million in 2009.

**Table of Contents***Business Operating Income*

Business operating income for 2010 was 12,863 million, compared to 12,076 million in 2009. The table below shows trends in business operating income by business segment for 2010 and 2009:

<i>( million)</i>	<b>2010</b>	<b>2009</b>
Pharmaceuticals	10,965	10,608
Vaccines	1,379	1,173
Animal Health	621	288
Other	(102)	7
<b>Business operating income</b>	<b>12,863</b>	<b>12,076</b>

*Business Net Income*

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance (see Item 5. Operating and Financial Review and Prospects - Business Net Income - above).

Business net income for 2010 was 9,215 million, an improvement of 6.8% on the 2009 figure of 8,629 million, and represented 28.5% of net sales compared with 29.0% in 2009. The increase was mainly due to our good operating performance, reflected in the increase in gross profit (24,638 million in 2010 versus 23,125 million in 2009).

<i>( million)</i>	<b>2010 <sup>(1)</sup></b>	<b>2009 <sup>(1)</sup></b>
<b>Business net income</b>	<b>9,215</b>	<b>8,629</b>
(i) Amortization of intangible assets	(3,529)	(3,528)
(ii) Impairment of intangible assets	(433)	(372)
(iii) Fair value remeasurement of contingent consideration liabilities		
(iv) Expenses arising from the impact of acquisitions on inventories <sup>(2)</sup>	(142)	(90)
(v) Restructuring costs	(1,384)	(1,080)
(vi) Other gains and losses, and litigation <sup>(3)</sup>	(138)	
(vii) Impact of the non-depreciation of the property, plant & equipment of Merial (IFRS 5)	77	21
(viii) Tax effects on the items listed above, comprising:	1,856	1,644
- amortization of intangible assets	1,183	1,130
- impairment of intangible assets	143	136
- expenses arising from the impact of acquisitions on inventories	44	24
- restructuring costs	466	360
- other gains and losses, and litigation	46	
- non-depreciation of property, plant and equipment of Merial (IFRS 5)	(26)	(6)
(iv)/(ix) Other tax items <sup>(4)</sup>		106
(x) Share of items listed above attributable to non-controlling interests	3	1
(iv)/(v) Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures <sup>(5)</sup>	(58)	(66)
<b>Net income attributable to equity holders of Sanofi</b>	<b>5,467</b>	<b>5,265</b>

<sup>(1)</sup> The results of operations of Merial, which was previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough will be maintained as two separate businesses operating independently (see note D.2. to our consolidated financial statements included at Item 18 of this annual report).



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- (2) This line comprises the workdown of inventories remeasured at fair value at the acquisition date.
- (3) See note D.28. to our consolidated financial statements included at Item 18 of this annual report.
- (4) In 2009: reversal of deferred taxes following ratification of the Franco-American Treaty.
- (5) This line shows the portion of major restructuring costs incurred by associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill).

**Business Earnings Per Share**

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see Business Net Income above).

Business earnings per share for 2010 were 7.06, up 6.8% on the 2009 business earnings per share figure of 6.61. The weighted average number of shares outstanding was 1,305.3 million in 2010 and 1,305.9 million in 2009. Diluted business earnings per share for 2010 were 7.04, up 6.7% on the 2009 diluted business earnings per share figure of 6.60. On a diluted basis, the weighted average number of shares outstanding was 1,308.2 million in 2010 and 1,307.4 million in 2009.

**Liquidity and Capital Resources**

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow, and pay regular dividends on our shares. During the course of 2011, our debt significantly increased to finance the acquisition of Genzyme. As of December 31, 2011, our debt, net of cash and cash equivalents, stood at 10,859 million (19.3% of our net equity) versus 1,577 million as of December 31, 2010 (3.0% of our net equity) and 4,128 million as of December 31, 2009 (8.5% of our net equity). See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

**Consolidated Statement of Cash Flows**

The table below shows our summarized cash flows for the years ended December 31, 2011, 2010 and 2009:

( million)	2011	2010	2009
Net cash provided by / (used in) operating activities	9,319	9,859	8,602
Net cash provided by / (used in) investing activities	(14,701)	(3,475)	(7,327)
Net cash provided by / (used in) financing activities	2,893	(4,646)	(788)
Impact of exchange rates on cash and cash equivalents	1	55	27
Impact of the cash and cash equivalents of Merial <sup>(1)</sup>	147		
<b>Net change in cash and cash equivalents (decrease) / increase</b>	<b>(2,341)</b>	<b>1,793</b>	<b>514</b>

<sup>(1)</sup> See Note D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

Generally, factors that affect our earnings—for example, pricing, volume, costs and exchange rates—flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Receipts of royalty payments also contribute to cash from operations.

*Year Ended December 31, 2011 Compared with Year Ended December 31, 2010*

**Net cash provided by operating activities** totaled 9,319 million in 2011, compared with 9,859 million in 2010. In 2011, operating cash flow before changes in working capital was 9,834 million versus 10,024 million in 2010.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect Operating income, which is discussed in detail above under Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010 and Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009. The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

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Working capital requirements rose by 515 million in 2011, compared with an 165 million increase in 2010. The 2011 increase was related to increased inventories ( 232 million) and trade receivables ( 257 million), following the consolidation of Genzyme and Merial.

**Net cash used in investing activities** totaled 14,701 million in 2011, versus 3,475 million in 2010.

Acquisitions of property, plant and equipment and intangible assets amounted to 1,782 million (compared with 1,662 million in 2010) and included Genzyme investments from April 2011. These mainly corresponded to investments in industrial and research facilities (1,394 million compared with 1,261 million in 2010) as well as contractual payments for intangible rights under licensing or collaboration agreements ( 182 million versus 312 million in 2010).

Financial investments for 2011 totaled 13,616 million, net of cash from acquired companies. Including assumed liabilities and commitments, these were valued at 14,079 million and regarded mainly the acquisition of Genzyme ( 13,602 million) and BMP Sunstone ( 374 million). In 2010, financial investments were 1,733 million net of acquired cash; they were valued, after including assumed liabilities and commitments, at 2,130 million, primarily covering the acquisition of equity interests in Chattem ( 1,640 million) and Nepentes ( 104 million).

After-tax proceeds from disposals amounted to 359 million, coming mainly from the sale of the Dermik dermatology business ( 321 million). In 2010, proceeds from disposals accounted for 136 million net of taxes, mainly from the sale divestment of the equity interest in Novoxel ( 48 million) and on the disposal of various tangible assets ( 55 million).

**Net cash used in financing activities** yielded a positive balance in 2011 of 2,893 million, compared with a negative balance in 2010 of 4,646 million. In 2011, these specifically included 5,283 million in outside funding (net change in short-term and long-term debt) compared with 1,165 million in debt repayments in 2010, our dividend payout of 1,372 million to Sanofi shareholders (versus 3,131 million in 2010), and the acquisition of 21.7 million of our own shares for 1,074 million.

After the impact of exchange rates and the impact of the cash and cash equivalents of Merial, the net change in cash and cash equivalents during 2011 was a decline of 2,341 million, versus a 1,793 million increase in 2010.

*Year Ended December 31, 2010 Compared with Year Ended December 31, 2009*

**Net cash provided by operating activities** amounted to 9,859 million in 2010, compared with 8,602 million in 2009. Operating cash flow before changes in working capital was 10,024 million, versus 9,384 million in 2009, reflecting our operating performance.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect Operating income, which is discussed in detail above under Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 and Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008. The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.



Working capital requirements rose by 165 million in 2010, compared with an 782 million increase in 2009. The main factor in 2010 was a 386 million rise in inventories, partly offset by the discontinuation of royalty payments from Teva on North American sales of Copaxone® (impact: 126 million) and the integration of Merial's net current liabilities.

**Net cash used in investing activities** totaled 3,475 million in 2010, versus 7,327 million in 2009.

Acquisitions of property, plant and equipment and intangible assets amounted to 1,662 million (2009: 1,826 million), comprising 1,350 million of investments in industrial and research facilities and 312 million of contractual payments for intangible rights under licensing or collaboration agreements.

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Financial investments during 2010 totaled 1,733 million, net of acquired cash; after including assumed liabilities and commitments, these acquisitions were valued at 2,130 million. Our main investment during 2010 was the equity interest in Chattem ( 1,640 million). In 2009, acquisitions of investments were 5,568 million, net of acquired cash; after including assumed liabilities and commitments, these acquisitions were valued at 6,334 million. Our main investments in 2009 were the equity interests in Merial ( 2,829 million), Zentiva ( 1,752 million), Shantha, Medley, and BiPar.

After-tax proceeds from disposals amounted to 136 million, arising mainly on the divestment of the equity interest in Novoxel ( 48 million) and on the disposal of various items of property, plant and equipment ( 55 million). In 2009, after-tax proceeds from disposals were 87 million, mainly on disposals of intangible assets, some of which were required as conditions for clearance of our acquisition of Zentiva.

**Net cash used in financing activities** amounted to 4,646 million in 2010, versus 788 million in 2009.

The 2010 figure includes our dividend payout of 3,131 million (2009: 2,872 million), plus net repayments of debt (net change in short-term and long-term debt) of 1,165 million (versus a net 1,922 million of new debt contracted in 2009). It also includes the acquisition of 5.9 million of our own shares for 321 million.

After the impact of exchange rates and the impact of the cash and cash equivalents of Merial, the net change in cash and cash equivalents during 2010 was an increase of 1,793 million, compared with an increase of 514 million in 2009.

### *Consolidated Balance Sheet and Debt*

Total assets stood at 100,165 million as of December 31, 2011, compared with 85,264 million as of December 31, 2010, an increase of 14,901 million.

Our **debt, net of cash and cash equivalents** was 10,859 million as of December 31, 2011, versus 1,577 million as of December 31, 2010. We define debt, net of cash and cash equivalents as short-term and long-term debt, plus related interest rate and currency derivatives, minus cash and cash equivalents. Debt, net of cash and cash equivalents, is a non-GAAP financial measure that is used by management and investors to measure the Company's overall net indebtedness and to assess the Company's financing risk as measured by its gearing ratio (debt, net of cash and cash equivalents, to total equity). See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

The table below shows our financial position for the years ended December 31, 2011, 2010 and 2009:

( million)	2011	2010	2009
Long-term debt	12,499	6,695	5,961
Short-term debt and current portion of long-term debt	2,940	1,565	2,866
Cash and cash equivalents	(4,124)	(6,465)	(4,692)
Related interest rate and currency derivatives	(456)	(218)	(7)

<b>Debt, net of cash and cash equivalents</b>	<b>10,859</b>	<b>1,577</b>	<b>4,128</b>
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The gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) rose from 3.0% on December 31, 2010 to 19.3% on December 31, 2011; this change was due to financing arrangement for the Genzyme acquisition in the first half of 2011. For an analysis of our debt by type, maturity, interest rate and currency as of December 31, 2011 and December 31, 2010, refer to Note D.17. to our consolidated financial statements.

The financing arrangements in place as of December 31, 2011 at the Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking credit spreads or fees to our credit rating. Under the Bridge Facility, the margin above Libor and mandatory costs may vary under Facility B as a function of our credit rating (see Item 10.C. hereof for further information).

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Other key movements in balance sheet items are described below.

Total equity stood at 56,389 million as of December 31, 2011, compared with 53,288 million a year earlier. The main factors underlying this net increase were as follows:

increases: net income for the year ended December 31, 2011 ( 5,693 million), and the impact of capital increases to pay share dividends, net of share buybacks ( 816 million); and

reductions: dividend payments to our shareholders (payment of dividends for fiscal year 2010 of 3,262 million).

As of December 31, 2011, Sanofi held 17.2 million of its own shares, recorded as a deduction from equity and representing 1.3% of the share capital.

Goodwill and other intangible assets ( 61,718 million) increased by 17,307 million compared to a year earlier, mainly as a result of the following factors:

increases: the impact of company acquisitions ( 4,361 million of goodwill, and 10,446 million of other intangible assets), mainly Genzyme, the reclassification of Merial's assets previously reported as held for sale or exchange ( 1,210 million of goodwill and 3,979 million of other intangible assets), and the euro revaluation of assets denominated in other currencies ( 1,276 million, primarily on the U.S. dollar);

reductions: amortization and impairment losses for the period ( 3,976 million).

Provisions and other non-current liabilities ( 10,346 million) were 1,020 million higher than at the previous year-end, mainly due to the increase in actuarial gains and losses associated with provisions and other benefits ( 677 million), the impact of the recent consolidation of new companies (Genzyme and BMP Sunstone) and the reclassification of Merial's provisions previously reported as assets held for sale or exchange.

Net deferred tax liabilities ( 2,378 million) were up 1,621 million in 2011; they increased on the one hand due to the consolidation of new companies, mainly Genzyme and Merial, and decreased on the other hand from the reversal of deferred tax liabilities associated with the amortization and impairment of acquired intangible assets ( 1,529 million).

Liabilities related to business combinations and to non-controlling interests, both current and non-current, ( 1,556 million) increased by 1,070 million due to the 2011 recognition of a price consideration to Bayer and contingent value rights (CVR) resulting from the acquisition of Genzyme (see Note D.18. to our consolidated financial statements).

The change in net assets held for sale or exchange ( 47 million versus 5,364 million as of December 31, 2010) was related to the reclassification of Merial's net assets ( 5,347 million) to each line item on the balance sheet based on its type (see Note D.8.1. to our consolidated financial

statements).

***Liquidity***

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year-end 2011, we held cash and cash equivalents amounting to 4,124 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements). As at December 31, 2011, 460 million of our cash and cash equivalents were held by our captive insurance and reinsurance companies in accordance with insurance regulations.

Since the beginning of 2010, certain Southern European countries have encountered increasing financial difficulties, particularly Greece and Portugal, where part of our customers are government-owned or supported healthcare facilities. Deteriorating credit and economic conditions and other factors in these countries have resulted in, and may continue to result in an increase in the average length of time taken to collect these accounts receivable and may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We are conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payments plans, charging of interest for late payments, and legal action. See

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Item 3.D. Risks Factors Risks Relating to Our Business We are subject to the risk of non-payment by our customers and Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Group's results of operations and financial results .

At year-end 2011, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of 10.0 billion at December 31, 2011. For a discussion of our treasury policies, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights ( CVR ). As of December 31, 2011, Sanofi had purchased 2,120,897 CVRs (for a total consideration of \$2.6 million) out of 291,313,510 issued at the time of the Genzyme acquisition.

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

**Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments**

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2011 are shown in Notes D.3., D.17., D.18. and D.21. to our consolidated financial statements included at Item 18 of this annual report. Note D.21. to our consolidated financial statements included at Item 18 discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.e) to our 2011 consolidated financial statements.

The Group's contractual obligations and other commercial commitments are set forth in the table below:

December 31, 2011	Total	Payments due by period			
		Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
( million)					
Future contractual cash-flows relating to debt and debt hedging instruments <sup>(1)</sup>	16,495	3,121	6,496	3,680	3,198
Operating lease obligations	1,456	284	406	245	521
Finance lease obligation <sup>(2)</sup>	123	19	40	35	29
Irrevocable purchase commitment <sup>(3)</sup>					
- given	3,041	1,672	608	325	436
- received	(247)	(105)	(76)	(42)	(24)
Research & development license agreements					
- Future service commitments <sup>(4)</sup>	944	196	307	416	25
- Potential milestone payments <sup>(5)</sup>	2,822	175	297	444	1,906
Obligations relating to business combinations <sup>(6)</sup>	5,578	496	1,144	718	3,220
Estimated benefit payments on unfunded pensions and post employment	1,453	64	121	140	1,128

benefits <sup>(7)</sup>					
<b>Total contractual obligations and other commitments</b>	<b>31,665</b>	<b>5,922</b>	<b>9,343</b>	<b>5,961</b>	<b>10,439</b>
<b>Undrawn general-purpose credit facilities</b>	<b>10,046</b>	<b>3,046</b>		<b>7,000</b>	

<sup>(1)</sup> See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(2)</sup> See Note D.3. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(3)</sup> These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3. to our consolidated financial statements included at Item 18 of this annual report) and (ii) goods and services.

<sup>(4)</sup> Future service commitments relating to research & development license agreements mainly comprise research financing commitments, but also include consideration for access to technologies.

<sup>(5)</sup> This line includes all potential milestone payments on projects regarded as reasonably possible, i.e., on projects in the development phase. Payments contingent upon the attainment of sales targets once a product is on the market are excluded.

<sup>(6)</sup> See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(7)</sup> See Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report. The table above does not include the ongoing annual employer's contributions to plan assets, estimated at 353 million in 2012.

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We may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects in the Pharmaceuticals segment are described below. Milestone payments relating to development projects under these agreements amounted to 2.1 billion in 2011. These exclude projects in the research phase ( 4.2 billion in 2011) and payments contingent upon the attainment of sales targets once a product is on the market ( 4.4 billion in 2011).

Following the Genzyme acquisition in April 2011, Sanofi took over a commitment towards Isis Pharmaceuticals Inc. This collaboration agreement was signed in January 2008 and enabled to obtain an exclusive license to develop and commercialize Mipomersen, a treatment in advanced development phase used in severe familial hypercholesterolemia.

In May 2011, Sanofi signed a license agreement with Glenmark Pharmaceuticals S.A. (Glenmark), a wholly-owned subsidiary of Glenmark Pharmaceuticals Limited India, to develop and commercialize GBR500, a novel monoclonal antibody for the treatment of Crohn's disease and other chronic auto-immune diseases.

In June 2010 Sanofi signed an exclusive global collaboration and license agreement with Ascenta Therapeutics, a U.S. biopharmaceutical company, on a number of molecules that could restore apoptosis (cell death) in tumor cells.

At the end of April 2010, Sanofi signed a license agreement with Glenmark for the development and commercialization of novel agents to treat chronic pain. Those agents are vanilloid receptor (TRPV3) antagonist molecules, including a first-in-class clinical compound, GRC 15300, which is currently in Phase I clinical development.

In April 2010, Sanofi signed a global license agreement with CureDM Group Holdings, LLC for Pancreat , a novel human peptide which could restore a patient's ability to produce insulin and other pancreatic hormones in both type 1 and 2 diabetes.

In December 2009, Sanofi and the U.S. biotechnology company Alopexx Pharmaceuticals LLC simultaneously signed (i) a collaboration agreement, and (ii) an option for a license on an antibody for the prevention and treatment of infections originating in the



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bacterium that causes plague and other serious infections.

At end September 2009, Sanofi and Merrimack Pharmaceuticals Inc. signed an exclusive global licensing and collaboration agreement covering the MM-121 molecule for the management of solid malignancies.

In May 2009, Sanofi signed a global license agreement in oncology with the biotechnology company Exelixis, Inc. for XL147 and XL765. Simultaneously Sanofi signed an exclusive research collaboration agreement for the discovery of inhibitors of Phosphoinositide-3 Kinase (PI3K) for the management of malignant tumors, that was terminated on December 22, 2011.

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May 2009: collaboration and licensing agreement with Kyowa Hakko Kirin Co., Ltd, under which Sanofi obtained the worldwide rights to the anti-LIGHT fully human monoclonal antibody. This anti-LIGHT antibody is presently at preclinical development stage, and is expected to be first-in-class in the treatment of ulcerative colitis and Crohn's disease.

In September 2003, Sanofi signed a collaboration agreement in oncology with Regeneron Pharmaceuticals Inc. (Regeneron) to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Under the terms of the agreement, Sanofi will pay 100% of the development costs of the VEGF Trap. Once a VEGF Trap product starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by Sanofi) in accordance with a formula based on Regeneron's share of the profits.

In November 2007, Sanofi signed another collaboration agreement with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies. This agreement was broadened, and its term extended; on November 10, 2009. Under the terms of the development agreement, Sanofi committed to fund 100% of the development costs of Regeneron's antibody research program until 2017. Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) half of the development costs borne by Sanofi.

Sanofi has also entered into the following major agreements, which are currently in a less advanced research phase:

In June 2011, Sanofi signed an exclusive worldwide research collaboration agreement and option for license with Rib-X Pharmaceuticals, Inc. (Rib-X) for novel classes of antibiotics resulting from the Rib-X's RX-04 program for the treatment of resistant Gram-positive and resistant Gram-negative pathogens.

December 2010: a global licensing and patent transfer agreement with Ascendis Pharma (Ascendis) on the proprietary Transcon Linker and Hydrogel Carrier technology developed by Ascendis for precise, time-controlled release of therapeutic active ingredients into the body. The agreement will enable Sanofi to develop, manufacture and commercialize products combining this technology with active molecules for the treatment of diabetes and related disorders.

December 2010: alliance with Avila Therapeutics Inc. (Avila) to discover target covalent drugs for the treatment of cancers, directed towards six signaling proteins that are critical in tumor cells. Under the terms of the agreement, Sanofi will have access to Avila's proprietary Avilomics™ platform offering protein silencing for these pathogenic proteins.

December 2010: an exclusive global licensing option with Oxford BioTherapeutics for three existing antibodies, plus a research and collaboration agreement to discover and validate new targets in oncology.

September 2010: alliance with the Belfer Institute of Applied Cancer Science at the Dana-Farber Cancer Institute (DFCI) to identify novel targets in oncology for the development of new therapeutic agents directed towards these targets and their associated biomarkers. Under the terms of the agreement, Sanofi will have access to the Belfer Institute's anticancer target identification and validation platform and to its translational medicine resources. Sanofi also has an option over an exclusive license to develop, manufacture and commercialize novel molecules directed towards the targets identified and validated under this research collaboration.

June 2010: alliance with Regulus Therapeutics Inc. to discover, develop and commercialize novel micro-RNA therapeutics, initially in fibrosis. Sanofi also received an option, which if exercised, would provide access to the technology to develop and commercialize other micro-RNA based therapeutics, beyond the first four targets.

October 2009: agreement with Micromet, Inc. to develop a BiTE® antibody against a tumor antigen present at the surface of carcinoma cells.

In the Vaccines segment, Sanofi Pasteur has entered into a number of collaboration agreements. Milestone payments relating to development projects under those agreements amounted to 0.3 billion in 2011.

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In December 2009, Sanofi Pasteur signed a donation letter to the World Health Organization (WHO). The terms of the agreement committed Sanofi Pasteur to donate 10% of its future output of vaccines against A(H1N1), A(H5N1) or any other influenza strain with pandemic potential, up to a maximum of 100 million doses. Since this agreement was put in place, Sanofi Pasteur has already donated to the WHO some of the doses covered by the commitment.

### **Critical accounting and reporting policies**

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

**Revenue recognition.** Our policies with respect to revenue recognition are discussed in Note B.14. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement under Net sales. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to charge back incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions of the attainment of sales targets. They are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. We also estimate the amount of product returns, on the basis of contractual sales terms and reliable historical data; the same recognition principles apply to sales returns. For additional details regarding the financial impact of discounts, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group, are presented in Other revenues.

**Business combinations.** As discussed in Note B.3. Business combinations and transactions with non-controlling interests to our consolidated financial statements included at Item 18 of this annual report, business combinations are accounted for by the acquisition method. The acquiree's identifiable assets, liabilities and contingent liabilities that satisfy the recognition criteria of IFRS 3 Business combinations are measured initially at their fair values as at the acquisition date, except for non-current assets classified as held for sale, which are measured at fair value less costs to sell. Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27, Consolidated and individual financial statements. In particular, contingent consideration to former owners agreed in a business combination, e.g. in the form of milestone payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date. Any subsequent changes in amounts recorded as a liability are recognized in the consolidated income statement.

**Goodwill impairment and intangible assets.** As discussed in Note B.6. Impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures and in Note D.5.

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Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets periodically for impairment. We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Key assumptions relating to goodwill impairment and intangible assets are the perpetual growth rate and the post-tax discount rate. Any changes in key assumptions could result in an impairment charge. A sensitivity analysis to the key assumptions is performed and disclosed in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report.

**Pensions and post-retirement benefits.** As described in Note B.23. Employee benefit obligations to our consolidated financial statements included at Item 18 of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the potential rights vested in employees and retirees as of the balance sheet date, net of the valuation of funds to meet these obligations. We prepare this estimate at least on an annual basis, taking into account actuarial assumptions, including life expectancy, staff turnover, salary growth, long-term return on plan assets, retirement and discounting of amounts payable. Pensions and post-retirement benefits key assumptions are the discount rate and the expected long term rate of return on plan assets.

Depending on the discount rate used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on equity because in applying IAS 19 (Employee Benefits), we have elected to recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity. A sensitivity analysis to discount rate is performed in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

Depending on the expected long term rate of return on plan assets used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to expected long term rate of return is performed in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

**Deferred taxes.** As discussed in Note B.22. Income tax expense to our consolidated financial statements included at Item 18 of this annual report, we account for deferred taxes using the liability method, whereby deferred income taxes are recognized on tax loss carry-forwards, and on the difference between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The estimates of recognized deferred tax assets are based on our assumptions regarding future profits and the timing of reversal of temporary differences. These assumptions are regularly reviewed; however, final deferred income tax could differ from those estimates.

**Provisions for risks.** Sanofi and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. Provisions for risks at Item 18 of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; when it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and when a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.19.3. Other provisions and D.22. Legal and Arbitral Proceedings to our consolidated financial statements included at Item 18 of this annual report.

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Provisions are estimated on the basis of events and circumstances related to present obligations at the balance sheet date, of past experience, and to the best of management's knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

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### **Item 6. Directors, Senior Management and Employees**

#### **A. Directors and Senior Management**

The offices of Chairman and Chief Executive Officer have been separated since January 1, 2007. While this decision was initially adopted out of a desire to ensure an orderly succession in light of the scheduled departure of Jean-François Dehecq, who was nearing the mandatory age limit set in the Company's Articles of Association, the annual evaluations conducted since have indicated that this governance structure is suitable to the Group's current configuration. This arrangement was thus continued with the appointment of Serge Weinberg to the office of Chairman on May 17, 2010 and again with his reappointment on May 6, 2011. The Board of Directors considers that this governance structure is appropriate in the Group's current context.

The **Chairman** represents the Board of Directors. The Chairman organizes and directs the work of the Board and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance practices. The Chairman coordinates the work of the Board of Directors with its Committees. The Chairman is accountable to the Shareholders' General Meeting, which he presides.

When the offices of Chairman and Chief Executive Officer are separated, the Chairman may remain in office until the Ordinary Shareholders' General Meeting called to approve the financial statements held during the calendar year in which he reaches the age of 70.

The Board of Directors has not deemed it necessary to appoint a lead independent director, since such role has been broadly assumed by Serge Weinberg. No element other than his chairmanship is of a nature which puts into question his independence, in particular given that prior to joining the Board Serge Weinberg did not have any ties to Sanofi.

The **Chief Executive Officer** is responsible for the management of the Company, and represents the Company in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and the Shareholders' General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer must be no more than 65 years old.

#### ***Limitations to the powers of the Chief Executive Officer set by the Board***

The Board of Directors Meeting of July 28, 2009 set limits on the powers of the Chief Executive Officer. The prior authorization of the Board of Directors is required to commit Sanofi to investments, acquisitions and divestments in the following cases:

- a 500 million cap for each undertaking pertaining to a previously approved strategy; and



- a 150 million cap for each undertaking not pertaining to a previously approved strategy.

When the consideration payable to the contracting parties for such undertakings includes potential installment payments subject to the achievement of future results or objectives, such as the registration of one or more products, the caps are calculated by adding the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

### ***Board of Directors***

The Company is administered by a Board of Directors comprised currently of fifteen members.

Since May 14, 2008, the terms of office of the directors have been staggered, in order to ensure that the directors are progressively re-elected between 2010 and 2012.

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and the composition of its Committees, in particular, the Board seeks to ensure a balanced

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representation of men and women, diversity of background and country of origin, since the business of the Group is both diversified and global. The Board also investigates and evaluates the potential candidates as well as each time individual directors are up for election. Above all, the Board seeks talented directors, who show independence of mind and who are competent, present and involved.

Under the terms of the AFEP-MEDEF corporate governance code, a director is deemed to be independent when the director has no relationship of any nature whatsoever with the Company, the group it belongs to or its senior management which could compromise the exercise of the director's freedom of decision. More specifically, independent directors are required:

- not to be an employee, nor a corporate officer of the Company, nor a corporate officer of a related company,
- not to be a customer, supplier nor a banker with respect to the business or financing of the Company,
- not to have close family ties with any corporate officer of the Company,
- not to have acted as auditor for the Company over the course of the last five years,
- not to have been a director of Sanofi for more than 12 years,
- not to be representative of a significant shareholder or control person of the Company.

In conformity with the Board Charter and pursuant to the AFEP-MEDEF corporate governance code, a discussion as to the independence of the current directors took place during the meeting of the Board of Directors of December 13, 2011. Of the fifteen directors, eight were deemed to be independent directors having regard to the independence criteria set forth in the AFEP-MEDEF corporate governance code: Uwe Bicker, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Suet-Fern Lee, Carole Piwnica, Klaus Pohle, and Gérard Van Kemmel.

In its examination of the independence of each Director, the Board of Directors took into account the various relationships that could exist between Directors and the Group and concluded that no such relationships were of a nature that could put into question their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the last three years, sold products and provided services with, and/or purchased products and received services from, companies in which certain of the Company's directors who are classified as independent or members of their close family were senior managers or employees during the financial year 2011. Each time, the amounts paid or received from such companies over the past three years were determined in accordance with normal course of business and did not represent amounts that the Board considered to be of such nature as to bring into question the independence of the directors in question. In the same manner, the Board of Directors did not find the office of trustee held by Uwe Bicker and Klaus Pohle with the Aventis Foundation (Germany) was of such nature as to bring into question their independence with respect to the Sanofi Board of Directors.

No more than one-third of the serving members of our Board of Directors may be over 70 years of age.

Subject to the powers expressly attributed to the Shareholders' General Meeting and within the scope of the Company's corporate purpose, the Board of Directors' powers cover all issues relating to the proper management of the Company and through its decisions determines all matters falling within its authority.

**Composition of the Board of Directors as of December 31, 2011**

Positions held in listed companies are flagged by an asterisk.

<b>Serge Weinberg</b>	Date of birth	<i>February 10, 1951</i>
Chairman of the Board	Nationality	<i>French</i>
	First elected	<i>December 2009</i>
	Last reappointment	<i>May 2011</i>
1,566 shares	Term expires	<i>2015</i>

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Other current directorships and appointments

Chairman of the Appointments and Governance Committee and of the Strategy Committee of Sanofi\*  
 Chairman of Weinberg Capital Partners, Financière Piasa and Piasa Holding  
 Director of VL Holding  
 Manager of Alret and Maremma  
 Member of the Supervisory Board of Financière BFSA  
 Vice Chairman and Director of Financière Poinsetia and Financière Sasa  
 Member of the Supervisory Board of Schneider Electric\*  
 Weinberg Capital Partners representative on the Board of Alliance Industrie and Sasa Industrie  
 Chairman of Corum (Suisse)

Education and business experience

Graduate in law  
 Degree from the *Institut d Etudes Politiques*  
 Studies at the *ENA (Ecole Nationale d Administration)*

1976-1982	<i>Sous-Préfet</i> and then Chief of Staff of the French Budget Minister (1981)
1982-1987	Deputy General Manager of FR3 (the French Television Channel) and then Chief Executive Officer of Havas Tourisme
1987-1990	Chief Executive Officer of Pallas Finance
1990-2005	Various positions at PPR* group including Chairman of the Management Board for 10 years

Past directorships held since 2007

Chairman of the Board of Accor\* (2006-2009)  
 Director of Alliance Industrie (2006-2008), of Road Holding (2007-2008) and of Rasec (2006-2010)  
 Member of the Board of Pharma Omnium International (2006-2010)  
 Member of the Supervisory Board of Rothschild & Cie (until 2010)  
 Member of the Supervisory Board of Gucci Group (Netherlands, until 2010)  
 Director of Fnac (until 2010) and of Rothschild Concordia (until 2010)  
 Vice Chairman of the Supervisory Board of Schneider Electric\* (until 2010)  
 Director of Team Partners Group (until 2011)  
 Member of the Supervisory Board Amplitude Group and Alfina (until 2011)

<b>Christopher Viehbacher</b>	Date of birth	<i>March 26, 1960</i>
Chief Executive Officer	Nationalities	<i>German and Canadian</i>
Director	First elected	<i>December 2008</i>
	Last reappointment	<i>May 2010</i>
95,442 shares	Term as director expires	<i>2014</i>

Other current directorships and appointments

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Chairman of the Executive Committee and Head of Global Leadership Team of Sanofi\*  
Member of the Strategy Committee of Sanofi\*  
Chairman of the Board of Directors of PhRMA (United States)  
Vice Chairman of EFPIA (Belgium)  
Member of the Board of Visitors of Fuqua School of Business, Duke University (United States)  
Member of the Board of Business Roundtable (United States)  
Member of the International Business Council, World Economic Forum (Switzerland)  
President of Genzyme (United States)  
Chairman of the CEO Roundtable on Cancer (United States)

### Education and business experience

B.A. in Commerce of Queens University (Ontario-Canada); certified public accountant  
Began his career at PricewaterhouseCoopers Audit

1988-2008                      Various positions at the GSK group, including President Pharmaceutical Operations for North America

**Table of Contents**Past directorships held since 2007

Director of GlaxoSmithKline plc\* (GSK plc) (United Kingdom, until November 2008)  
 Member of the Board of Triangle United Way (United States, 2003-2008), Cardinal Club (United States, 2004-2008) and GlaxoSmithKline NC Foundation (United States, 2003-2008)  
 Vice Chairman of Portfolio Management Board of GSK plc\* (United Kingdom, 2007-2008)  
 Manager of pharmaceutical operations of GSK plc\* in North America (until 2008)  
 Manager of pharmaceutical operations of GSK plc\* in United States (until 2008)  
 Member of Advisory Council of Center for Healthcare Transformation (United States, until 2010)  
 Chairman and Chief Executive Officer of Genzyme (United States, in 2011)  
 Chairman and member of the Board of Directors of Research America and Burroughs Wellcome Fund (United States, until 2011)

<b>Uwe Bicker</b>	Date of birth	<i>June 14, 1945</i>
Independent Director	Nationality	<i>German</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>
600 shares		

Other current directorships and appointments

Member of the Strategy Committee of Sanofi\*  
 Chairman of the Supervisory Board of Siemens Healthcare Diagnostics Holding GmbH (Germany)  
 Vice Chairman of the Supervisory Board of Epigenomics AG (Germany)  
 Member of the Supervisory Board of Future Capital AG (Germany) and Definiens AG (Germany)  
 Trustee of Fondation Aventis (not-for-profit, Germany)  
 Chairman of the Board of Marburg University (Germany)  
 Member of the Advisory Board of Morgan Stanley (Germany)

Education and business experience

Doctorate in chemistry and in medicine  
 Honorary Doctorate, Klausenburg University  
 Honorary Senator, Heidelberg University

1975-1994	Various positions at Boehringer Mannheim GmbH (later Roche AG)
1994-2004	Various positions at Hoechst group
Since 1983	Professor at the Medical Faculty of Heidelberg
Since 2011	Dean at the Medical Faculty, Heidelberg University Managing Director at the University Clinic of Mannheim

Past directorships held since 2007

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Chairman of the Supervisory Board of Dade Behring GmbH (2007)  
Member of the Board of Trustees of Bertelsmann Stiftung (Bertelsmann Foundation, Germany, until 2011)

<b>Robert Castaigne</b>	Date of birth	<i>April 27, 1946</i>
Director	Nationality	<i>French</i>
	First elected	<i>February 2000</i>
	Last reappointment	<i>May 2010</i>
	Term expires	<i>2014</i>
517 shares		

### Other current directorships and appointments

Member of the Audit Committee of Sanofi\*  
Director of Vinci\*and Société Générale\*  
Member of the Audit, Internal control and Risk Committee of Société Générale\*  
Member of the Audit Committee of Vinci\*

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**Education and business experience**

Degree from the *Ecole Centrale de Lille* and the *Ecole Nationale Supérieure du Pétrole et des Moteurs*  
 Doctorate in economics

1972-2008                      Various positions at the Total\* group, including Chief Financial Officer and member of the Executive Committee  
 (June 1994 – May 2008)

**Past directorships held since 2007**

Chairman and Chief Executive Officer of Total Chimie (1996-2008) and of Total Nucléaire (1992-2008)  
 Director of Elf Aquitaine (2000-2008), of Hutchinson (1995-2008), of Total Gestion Filiales (1994-2008) of Omnium Insurance &  
 Reinsurance Company Ltd (Bermuda, 1996-2008), of Petrofina (Belgium, 1999-2008), of Total Upstream UK Ltd (United-Kingdom,  
 2005-2008), of Total Gabon (2003-2008) and of Petrofina (United-Kingdom, until 2008)  
 Director and Member of the Audit Committee of Compagnie Nationale à Portefeuille (Belgium, until 2011)  
 Member of the Remuneration Committee of Vinci\* (until 2009)

<b>Thierry Desmarest</b>	Date of birth	<i>December 18, 1945</i>
Director	Nationality	<i>French</i>
	First elected	<i>February 2000</i>
	Last reappointment	<i>May 2011</i>
517 shares	Term expires	<i>2015</i>

**Other current directorships and appointments**

Member of the Compensation Committee, the Appointments and Governance Committee and the Strategy Committee of Sanofi\*  
 Director and Honorary President of Total S.A.\*  
 Chairman of the Nominating and Governance Committee of Total S.A.\*  
 Member of the Compensation Committee and the Strategy Committee of Total S.A.\*  
 Chairman of *Fondation Total* (Foundation)  
 Director of L'Air Liquide\*, Renault SA\*, Renault SAS  
 Member of the Appointments and Governance Committee and the Compensation Committee of L'Air Liquide\*  
 Chairman of the International Strategy Committee, member of the Remuneration Committee and member of the Industrial Strategy  
 Committee of Renault SA\*  
 Director, member of the Appointments and Governance Committee, member of the Human Resources and Compensation Committee of  
 Bombardier Inc. (Canada)  
 Member of the Board of Directors of l'Ecole Polytechnique  
 Chairman of Fondation de l'Ecole Polytechnique (Foundation)  
 Director of Musée du Louvre



Education and business experience

Degree from *Ecole Polytechnique* and *Ecole Nationale Supérieure des Mines de Paris*

Since 1981                      Various positions at the Total\* group including Chairman and Chief Executive Officer (1995-2007). Chairman of the Board of Directors (February 2007-May 2010)

Past directorships held since 2007

Chairman and Chief Executive Officer of Elf Aquitaine (2000-2007)

Chairman and Chief Executive Officer of Total S.A.\* (1995-2007)

Chairman of the Board of Directors of Total S.A.\* (2007-2010)

Member of the Supervisory Board of Areva\* (2001-2010)

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<b>Lord Douro</b>	Date of birth	<i>August 19, 1945</i>
Independent Director	Nationality	<i>British</i>
	First elected	<i>May 2002</i>
	Last reappointment	<i>May 2010</i>
	Term expires	<i>2014</i>
2,000 shares		

**Other current directorships and appointments**

Member of the Appointments and Governance Committee and of the Strategy Committee of Sanofi\*  
 Chairman of Richemont Holdings UK Ltd and Kings College London (United Kingdom)  
 Director of Compagnie Financière Richemont AG\* (Switzerland) and GAM Worldwide (United Kingdom)  
 Member of the Appointments Committee and of the Compensation Committee of Compagnie Financière Richemont AG\* (Switzerland)  
 Advisor to Crédit Agricole CIB (United Kingdom)  
 Director of RIT Capital\* (United Kingdom)  
 Chairman of the Remuneration Committee and the Conflicts Committee of RIT Capital\* (United Kingdom)  
 Member of the Nominations Committee of RIT Capital\* (United Kingdom)  
 Member of the International Advisory Board of Abengoa SA\* (Spain, since April 1<sup>st</sup>, 2011)

**Education and business experience**

Master of Arts from Oxford University

1979-1989	Member of the European Parliament
1995-2000	Chairman of Sun Life & Provincial Holdings Plc*
1993-2005	Chairman of Framlington Group Ltd (United Kingdom)

**Past directorships held since 2007**

Commissioner of English Heritage (United Kingdom, until 2007)  
 Member of the Compensation Committee and the Appointments Committee of Pernod Ricard\* (until 2010)  
 Director of Pernod Ricard\* (until March 2011)  
 Director of Abengoa Bioenergy (until March 2011)

<b>Jean-René Fourtou</b>	Date of birth	<i>June 20, 1939</i>
Independent Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>

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Last reappointment	May 2008
Term expires	2012

4,457 shares

### Other current directorships and appointments

Member of the Compensation Committee, the Appointments and Governance Committee and the Strategy Committee of Sanofi\*  
Chairman of the Supervisory Board of Vivendi\*  
Member of the Supervisory Board of Maroc Telecom\* (Morocco)  
Director and member of the Compensation Committee of Nestlé\* (Switzerland)

### Education and business experience

Degree from the *Ecole Polytechnique*

1963-1986	Various positions at the Bossard group, including Chairman and Chief Executive Officer (1977-1986)
1986-1999	Chairman and Chief Executive Officer of Rhône-Poulenc*
1999-2004	Vice Chairman of the Management Board, Vice Chairman of the Supervisory Board and member of the Strategy Committee of Aventis*
2002-2005	Chairman and Chief Executive Officer of Vivendi*

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Past directorships held since 2007

Vice President then member of the Supervisory Board of Axa\* (1990-2009)  
 Member of the Ethics and Governance Committee of Axa\* (1990-2009)  
 Director of Cap Gemini\* (2005-2009)  
 Director of NBC Universal Inc. (United States, 2004-2010)  
 Vice Chairman, Chairman then Honorary Chairman of the International Chamber of Commerce (until 2008)  
 Chairman of the Supervisory Board of Group Canal +\* (France, until 2011)  
 Director of Axa Millésimes SAS (France, until 2011)

<b>Claudie Haigneré</b>	Date of birth	<i>May 13, 1957</i>
Independent Director	Nationality	<i>French</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>
500 shares		

Other current directorships and appointments

Member of the Compensation Committee and the Appointments and Governance Committee of Sanofi\*  
 Chairman of the Board of Directors of La Géode  
 Chairman of Universcience (*Cité des Sciences et de l' Industrie and Palais de la Découverte*)  
 Director of France Telecom\*, of *Fondation de France*, of *Fondation CGénial*, of *Fondation d' Entreprise L. Oréal* and of *Fondation Lacoste* (Foundations)  
 Member of *Académie des Technologies*, *Académie des Sports* and *Académie Nationale de l' Air et de l' Espace*  
 Member of the Strategy Committee of France Telecom\*

Education and business experience

Rheumatologist, doctorate in sciences majoring in neurosciences  
 Selected in 1985 by CNES (French National Space Center) as a candidate astronaut

1984-1992	Rheumatologist, Cochin Hospital (Paris)
1996	Scientific space mission to the MIR space station (Cassiopeeé Franco-Russian mission)
2001	Technical and scientific space mission to the International Space Station (Andromède mission)
2002-2004	Deputy Minister for Research and New Technologies in French government
2004-2005	Deputy Minister for European Affairs

Past directorships held since 2007

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Counselor at the European Space Agency (until 2009)  
Director and Chairman of the Cité des Sciences et de l'Industrie (until 2009)  
Chairman of Palais de la découverte  
Director of Aéro Club de France (until 2011)  
Vice President of the IAA (International Academy of Astronautics until 2011)

<b>Igor Landau</b>	Date of birth	<i>July 13, 1944</i>
Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2011</i>
	Term expires	<i>2015</i>
12,116 shares		

### Other current directorships and appointments

Chairman of the Supervisory Board of Adidas-Salomon\* (Germany)  
Director of HSBC France and INSEAD  
Member of the Supervisory Board and the Audit Committee of Allianz AG\* (Germany)

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**Education and business experience**

Degree from the *Ecole des Hautes Etudes Commerciales* (HEC) and from INSEAD (Master of Business Administration)

1968-1970	Chief Executive Officer of the German subsidiary of La Compagnie du Roneo (Germany)
1971-1975	Management consultant at McKinsey (France)
1975-2004	Various positions at the Rhône-Poulenc group, including member of the Management Board of Aventis (1999-2002) and Chairman of the Management Board of Aventis (2002-2004)
2001-2005	Director of Essilor*
2002-2005	Director of Thomson* (now called Technicolor*)
2003-2006	Member of the Supervisory Board of Dresdner Bank (Germany)

**Past directorships held since 2007**

N/A

<b>Suet-Fern Lee</b>	Date of birth	<i>May 16, 1958</i>
Director	Nationality	<i>Singaporean</i>
	First elected	<i>May 2011</i>
	Term expires	<i>2015</i>

500 shares

**Other current directorships and appointments**

Director of Axa\*  
 Director of Macquarie International Infrastructure Fund Ltd\* (Bermuda)  
 Director of National Heritage Board (Singapore)  
 Director of Rickmers Trust Management Pte Ltd\* (Singapore)  
 Director of Stamford Corporate Services Pte Ltd (Singapore)  
 Chairman of the Board of directors of the Asian Civilisations Museum (Singapore)

**Education and business experience**

Law degree from Cambridge University (1980)  
 Admitted to London (1981) and Singapore (1982) Bars

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Senior Partner of Stamford Law Corporation (Singapore)

Since 2008 President of the Inter-Pacific Bar Association (Singapore)  
Since 2006 Member of the Board of trustees of Nanyang Technological University (Singapore)  
Since 2006 Member of the Accountant Advisory Board of the National University of Singapore Business School (Singapore)  
Since 2007 Member of the Advisory Committee of the Singapore Management University School of Law (Singapore)

### Past directorships held since 2007

Director of China Aviation Oil\* (Singapore) (2006-2008)  
Director of ECS Holdings Limited\* (Singapore) (2000 to 2007)  
Director of International Capital Investment Limited (Singapore) (2004 to 2007)  
Director of Media Asia Entertainment Group Limited (Hong Kong) (2004 to 2007)  
Director of Richina Pacific Limited\* (Bermuda) (2005 to 2009)  
Director of Sincere Watch\* (Hong Kong) (2005 to 2008)  
Director of Transcu Group Limited\* (Singapore) (2008 to 2010)  
Director of Transpac Industrial Holdings Limited\* (Singapore) (2004 to 2007)  
Director of Sembcorp Industries Ltd\* (Singapore) (2005 to 2011)

### **Christian Mulliez**

Director

Date of birth

*November 10,  
1960*

Nationality

*French*

First elected

*June 2004*

Last reappointment

*May 2010*

Term expires

*2014*

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1,391 shares

**Other current directorships and appointments**

Vice President, General Manager Administration and Finance of L Oréal\*  
 Chairman of the Board of Directors of Regefi  
 Director of DG 17 Invest, L Oréal USA Inc., The Body Shop International (United Kingdom) and Galderma Pharma (Switzerland)

**Education and business experience**

Degree from the *Ecole Supérieure des Sciences Economiques et Commerciales (ESSEC)*

1984-2002	Various positions at Synthélabo and then at Sanofi-Synthélabo, including Vice President Finance
Since 2003	Executive Vice President Administration and Finance at L Oréal*

**Past directorships held since 2007**

N/A

<b>Lindsay Owen-Jones</b>	Date of birth	<i>March 17, 1946</i>
Director	Nationality	<i>British</i>
	First elected	<i>May 1999</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2012</i>
15,000 shares		

**Other current directorships and appointments**

Member of the Compensation Committee, of the Appointments and Governance Committee and of the Strategy Committee of Sanofi\*  
 Chairman of the Board of Directors of Fondation d Entreprise L Oréal (Foundation)  
 Chairman of Alba Plus  
 Director of L Oréal\* (France) and Ferrari S.p.A. (Italy)



Education and business experience

Bachelor of Arts (Hons) from Oxford University and degree from INSEAD

Since 1969	Various positions at the L Oréal* group, including Chairman and Chief Executive Officer (1988-2006) and Chairman of the Board of Directors (2006-2011)
1989-2005	Director of BNP Paribas*
1988-2006	Chief Executive of L Oréal*
2001-2006	Vice-President and member of the Supervisory Board of L Air Liquide*
until 2006	Director of Galderma Pharma

Past directorships held since 2007

Vice-Chairman of the Board of Directors of L Air Liquide\* (2006-2009)

Chairman of the Board of Directors and Chairman of the Strategy and Implementation Committee of L Oréal\* (France, until 2011)

Chairman & Director of L Oréal USA Inc. (United States, until 2011) and L Oréal UK Ltd (United Kingdom, until 2011)

<b>Carole Piwnica</b>	Date of birth	<i>February 12, 1958</i>
Independent Director	Nationality	<i>Belgian</i>
	First elected	<i>December 2010</i>
500 shares	Term expires	<i>2012</i>

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Other current directorships and appointments

Director of Naxos UK Ltd (United Kingdom)  
 Director and Chairman of the Committee of Governance, Compensation and Appointment of Eutelsat Communications\*  
 Director of Louis Delhaize\* (Belgium), Big Red (United States), Elevance (United States) and Amyris Inc.\* (United States)

Education and business experience

Degree in law, Université Libre de Bruxelles  
 Masters in law, New York University  
 Admitted to Paris and New York Bars

1985-1991 Attorney at Proskauer, Rose (New York) and Shearman & Sterling (Paris) with practice in mergers and acquisitions  
 1991-1994 General Counsel of Gardini & Associés  
 1994-2000 Chief Executive Officer of Amylum France, then Chairman of Amylum Group  
 1996-2000 Director of Tate & Lyle Plc (United Kingdom)  
 1998-2004 Director of Spadel (Belgium)  
 2000-2006 Director and Vice-Chairman for Governmental Affairs  
 1996-2006 Chairman of the Liaison Committee and director of the CIAA (Confederation of the Food and Drink Industries of the European Union)  
 2000- 2006 Chairman of the Export Commission and director of the Association Nationale des Industries Alimentaires

Past directorships held since 2007

Director of Dairy Crest Plc\* (United Kingdom, 2007-2010)  
 Director of Toepfel GmbH (Germany, 1996-2010)  
 Member of the Ethical Committee of Monsanto\* (United States, 2006-2009)  
 Director, Chairman of the Corporate Responsibility Committee and member of the Compensation Committee of Aviva Plc\* (United Kingdom, until 2011)

<b>Klaus Pohle</b>		<i>November 3, 1937</i>
Independent Director	Date of birth	
	Nationality	<i>German</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>
2,500 shares	Term expires	<i>2012</i>

Other current directorships and appointments

Chairman of the Audit Committee of Sanofi\*  
Trustee of Fondation Aventis (not-for-profit, Germany)

Education and business experience

Doctorate in law from Frankfurt University (Germany)  
Doctorate in economics from Berlin University (Germany)  
Masters in law from Harvard University  
Professor of Business Administration at the Berlin Institute of Technology (Germany)

1966-1980	Various positions at the BASF group
1981-2003	Deputy Chief Executive Officer and Chief Financial Officer of Schering AG
2003-2005	Chairman of the German Accounting Standards Board

Past directorships held since 2007

Chairman of the Supervisory Board (in 2008), Vice-Chairman of the Supervisory Board, Chairman of the Audit Committee and member of the Appointments and Governance Committee (until 2008) of Hypo Real Estate Holding AG\*, Munich (Germany)

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Member of the Supervisory Board and Chairman of the Audit Committee of DWS Investment GmbH (Germany, until 2009)  
 Director of Labelux Group GmbH\* (Switzerland, until 2011)  
 Director and Chairman of the Audit Committee of Coty Inc\*., New York, (United States, until 2011)

<b>Gérard Van Kimmel</b>		<i>August 8, 1939</i>
Independent Director	Date of birth	
	Nationality	<i>French</i>
	First elected	<i>May 2003</i>
	Last reappointment	<i>May 2011</i>
	Term expires	<i>2015</i>
1000 shares		

Other current directorships and appointments

Chairman of the Compensation Committee, Member of the Audit Committee and the Appointments and Governance Committee of Sanofi\*  
 Director of Europacorp\*  
 Member of the Audit Committee of Europacorp\*

Education and business experience

Graduate of the *Ecole des Hautes Etudes Commerciales (HEC)*  
 MBA degree from the Stanford Business School

1966-1995	Various positions including President of Arthur Andersen and Andersen Consulting in France (1976-1995) and Chairman of the Board of Arthur Andersen Worldwide (1989-1994)
1996-1997	Senior advisor to French Finance Minister
1997-2006	Various positions at Cambridge Technology Partners (Chief Operating Officer) and at Novell* (President EMEA)
2004-2006	Europe Chairman of Novell*

Past directorships held since 2007

Director of Groupe Eurotunnel\* (France, until 2010)  
 Director of Eurotunnel NRS Holders Company Limited (United Kingdom, until 2010)

Several changes in the composition of the Board of Directors occurred in 2011. The co-optation of Carole Piwnica on December 15, 2010, was ratified at the Shareholders General Meeting held on May 6, 2011. Likewise, Suet-Fern Lee was appointed director of the Company during the Shareholders General Meeting held on May 6, 2011.

*Executive Committee*

The Executive Committee is chaired by the Chief Executive Officer.

The Committee meets once a month, and has the following permanent members:

**Christopher Viehbacher**, Chief Executive Officer;

**Olivier Charmeil**, Senior Vice President Vaccines;

**Jérôme Contamine**, Executive Vice President Chief Financial Officer;

**David-Alexandre Gros**, Vice President Chief Strategy Officer;

**Karen Linehan**, Senior Vice President Legal Affairs and General Counsel;

**Philippe Luscan**, Senior Vice President Industrial Affairs;

**Roberto Pucci**, Senior Vice President Human Resources;

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**Hanspeter Spek**, President Global Operations; and

**Elias Zerhouni**, President, Global Research and Development.

The name, business address, present principal occupation or employment and material occupations, positions, offices or employment for the past five years of each of the executive officers of Sanofi are set forth below. The business address and phone number of each such executive officer is c/o Sanofi, 54 rue La Boétie, 75008 Paris, France, +33 1 53 77 40 00. Unless otherwise indicated, each executive officer is a citizen of France.

*Christopher Viehbacher*

**Chief Executive Officer**

**Chairman of the Executive Committee**

*Date of birth: March 26, 1960*

Christopher Viehbacher was appointed as Chief Executive Officer on December 1, 2008, and is a member of the Strategy Committee.

For additional information regarding his professional education and business experience see Composition of the Board of Directors as of December 31, 2011 in A. Directors and Senior Management on this Item 6.

Christopher Viehbacher is a citizen of Germany and Canada.

*Olivier Charmeil*

**Senior Vice President Vaccines since January 1, 2011**

*Date of birth: February 19, 1963*

Olivier Charmeil is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*) and of the *Institut d Etudes Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l Union Européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various posts within the Group, including Chief Financial Officer (Asia) for Sanofi-Synthélabo in 1999 and *Attaché* to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the post of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed Senior Vice President Asia/Pacific, Pharmaceutical Operations in February 2006 and since January 1, 2008, Operations Japan have reported to him as well as Asia/Pacific and Japan Vaccines since February 2009. Since January 1, 2011, Olivier Charmeil has served as Senior Vice President Vaccines and a member of the Executive Committee.

*Jérôme Contamine*

**Executive Vice President Chief Financial Officer**

*Date of birth: November 23, 1957*

Jérôme Contamine is a Graduate of *École Polytechnique (X)*, and *ENSAE*, the national statistics and economics engineering school, affiliated with the Ministry of Finance (1982). He also graduated from the *ENA (Ecole Nationale d Administration)*. After four years at the *Cour des Comptes*, as a Senior State General Auditor, he joined Elf Aquitaine in 1988, as advisor to the Chief Financial Officer, and became Group Finance Director & Treasurer in 1991. He became the General Manager of Elf Petroleum Norway in 1995, after being named Deputy Vice President of Elf Upstream Division for Europe and the U.S. In 1999, he was appointed as a member of the taskforce for integration with Total, in charge of the reorganization of the merged entity, TotalFinaElf, and in 2000 became Vice President Europe and Central Asia, Upstream Division of Total. The same year, he joined Veolia Environnement as CFO and Deputy General Manager. In 2003, he was appointed Vice-President Senior Executive, Deputy Chief Executive Officer, Financial Director of Veolia Environnement. Jérôme Contamine joined Sanofi as Executive Vice President, Chief Financial Officer (CFO) of Sanofi in March 2009.

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### ***David-Alexandre Gros***

**Chief Strategy Officer** since September 2011

*Date of birth: July 23, 1972*

David-Alexandre Gros has a B.A. from Dartmouth College (1995), an M.D. from Johns Hopkins University School of Medicine (1999), and an M.B.A. from Harvard Business School (2002). He began his career in clinical research at the Department of Urology of the Johns Hopkins Hospital, from 1996 to 1999, and acquiring clinical experience as a Resident Physician at the University of Pennsylvania Health System from 1999 to 2000. He started his advisory career in 2002 at McKinsey & Company as an Associate, was promoted to Engagement Manager in 2004 and to Associate Principal in 2006. In late 2006, he was appointed Vice President at Merrill Lynch, serving healthcare clients on a wide range of strategic, corporate finance and merger & acquisition issues. In 2009, he joined Centerview Partners, in San Francisco, California, as a key advisor to pharmaceutical, biotechnology and diagnostic companies as a Principal and founding member of the Healthcare Investment Banking practice. David-Alexandre Gros joined Sanofi as Chief Strategy Officer in September 2011.

### ***Karen Linehan***

**Senior Vice President Legal Affairs and General Counsel**

*Date of birth: January 21, 1959*

Karen Linehan graduated from Georgetown University with Bachelor of Arts and Juris Doctorate degrees. Prior to practicing law, Ms. Linehan served on the congressional staff of the Speaker of the U.S. House of Representatives from September 1977 to August 1986. Until December 1990, she was an Associate in a mid-size law firm in New York. In January 1991, she joined Sanofi as Assistant General Counsel of its U.S. subsidiary. In July 1996, Ms. Linehan moved to Paris to work on international matters within the Group and she has held a number of positions within the Legal Department, most recently as Vice President Deputy Head of Legal Operations. She was appointed to her current position in March 2007.

Karen Linehan is a citizen of the United States of America and Ireland.

### ***Philippe Luscan***

**Senior Vice President Industrial Affairs**

*Date of birth: April 3, 1962*

Philippe Luscan is a graduate of the *École Polytechnique* and the *École des Mines* in Biotechnology in Paris. He began his career in 1987 as a Production Manager at Danone. In 1990, he joined the Group as Director of the Sanofi Chimie plant at Sisteron, France, and subsequently served as Industrial Director of Sanofi in the United States, as Vice President Supply Chain and as Vice President Chemistry in September 2006. He was appointed to his present position in September 2008.



***Roberto Pucci***

**Senior Vice President Human Resources**

*Date of birth: December 19, 1963*

Roberto Pucci has a Law degree from the University of Lausanne, Switzerland. He started his career in 1985 at Coopers & Lybrand in Geneva, Switzerland as an external auditor. He then joined Hewlett-Packard (HP) in 1987, where he held various positions in Human Resources in Switzerland and Italy including HR Manager for the European Headquarters and Human Resources Director in Italy. In 1999, he became Director, Compensation & Benefits for Agilent Technologies, a spin off from HP, and was appointed Vice President Human Resources Europe in 2003. In 2005 he moved to the United States to join Case New Holland, a subsidiary of the Fiat Group, as Senior Vice President, Human Resources, and was appointed, in 2007, Executive Vice President, Human Resources for the Fiat Group in Torino, Italy. Roberto Pucci joined Sanofi as Senior Vice President Human Resources in October 2009.

Roberto Pucci is a citizen of Italy and Switzerland.

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### ***Hanspeter Spek***

#### **President Global Operations**

*Date of birth: November 5, 1949*

Hanspeter Spek graduated from business school in Germany. In 1974, he completed a management training program at Pfizer International, and then joined Pfizer RFA as a junior product manager. He served in various positions at Pfizer RFA, including as manager of the marketing division. Mr. Spek joined Sanofi Pharma GmbH, a German subsidiary of Sanofi, in 1985 as Marketing Director, and served in various positions in Germany and then at Sanofi in France, before being named Senior Vice President Europe following the merger with Synthelabo in 1999. He served as Executive Vice President, International Operations from October 2000, to January 2003, when he was named in charge of worldwide operations of Sanofi-Synthelabo. He was appointed Executive Vice President, Pharmaceutical Operations in August 2004. Since November 2009, he has been President, Global Operations.

Hanspeter Spek is a citizen of Germany.

### ***Elias Zerhouni***

#### **President, Global Research and Development**

*Date of birth: April 12, 1951*

After completing his initial training in Algeria, Dr. Zerhouni continued his academic career at the Johns Hopkins University and Hospital (United States) where he is currently professor of Radiology and Biomedical engineering and senior adviser for Johns Hopkins Medicine. He served as Chair of the Russell H. Morgan Department of Radiology and Radiological Sciences, Vice Dean for Research and Executive Vice Dean of the School of Medicine from 1996 to 2002 before his appointment as Director of the National Institutes of Health of the United States of America from 2002 to 2008. Dr. Zerhouni was received as member of the U.S. National Academy of Sciences Institute of Medicine in 2000. He was recently appointed as Chair of Innovation at the College de France, elected member of the French Academy of Medicine in 2010 and received the Transatlantic Innovation Leadership award in December 2011. In February 2009, Sanofi named Dr. Zerhouni Scientific Advisor to the Chief Executive Officer and to the Senior Vice-President Research & Development. He was appointed President Global Research & Development and has served on the Executive Committee of Sanofi, since January 2011.

Dr. Zerhouni is a citizen of the United States of America.

As of December 31, 2011, none of the members of the Executive Committee had their principal business activities outside of Sanofi.

The Executive Committee is assisted by the Global Leadership Team, which represents the principal services of the Group. The Global Leadership Team is made up of the members of the Executive Committee and 35 additional senior managers.



**Table of Contents****B. Compensation****Compensation and pension arrangements for corporate officers**

Christopher Viehbacher has held the office of Chief Executive Officer of Sanofi since December 1, 2008. He was an outside appointment and has never had an employment contract with Sanofi distinct from his current office. The compensation of the Chief Executive Officer is determined by the Board of Directors upon the recommendation of the Compensation Committee with reference to compensation paid to the chief executive officers of major global pharmaceutical companies and of major companies in the CAC 40 stock market index. The Chief Executive Officer receives fixed compensation, benefits in kind, and variable compensation. In addition, he may be granted stock options and performance shares. Since 2009, in accordance with the AFEP-MEDEF corporate governance code, stock options and, when applicable, performance shares granted to the Chief Executive Officer are subject to performance conditions.

Serge Weinberg has held the office of Chairman of the Board of Directors since May 17, 2010. He was an outside appointment and has never had an employment contract with Sanofi distinct from his current office. The Chairman of the Board also chairs the Strategy Committee and the Appointments and Governance Committee. In accordance with the Board Charter and in close collaboration with the Senior Management, he represents the Company in high-level dealings with governmental bodies and with the Group's key partners, both nationally and internationally and participates in the defining of the major strategic choices of the Group especially as regards mergers, acquisitions and alliances. The Chairman and the Chief Executive Officer keep each other fully informed of their actions. The compensation of the Chairman of the Board of Directors consists solely of fixed compensation and benefits in kind and excludes any variable compensation, any awards of stock options and performance shares and any directors' attendance fees.

The compensation policy for the corporate officers is established by the Board of Directors upon the recommendation of the Compensation Committee.

The corporate officers do not receive directors' attendance fees in their capacity as directors. Thus, Christopher Viehbacher does not receive directors' attendance fees in his capacity of a member of the Strategy Committee. Similarly, Serge Weinberg does not receive directors' attendance fees in his capacity of chairman of the Appointments and Governance Committee or of chairman of the Strategy Committee.

**Serge Weinberg****Compensation awarded to Serge Weinberg**

(in euros)	2011	2010	2009
Compensation payable for the year (details provided in the table below)	709,463	480,158	6,215
Value of stock subscription options awarded during the year	N/A	N/A	N/A
Value of performance shares awarded during the year	N/A	N/A	N/A
<b>Total</b>	<b>709,463</b>	<b>480,158</b>	<b>6,215</b>

Compensation payable and paid to Serge Weinberg

(in euros)	2011		2010		2009	
	Payable	Paid	Payable	Paid	Payable	Paid
Fixed compensation <sup>(1)</sup>	700,000	700,000	439,748	439,748	N/A	N/A
Variable compensation	N/A	N/A	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A	N/A	N/A
Attendance fees	N/A	35,625	35,625	6,215	6,215	N/A
Benefits in kind	9,463	9,463	4,785	4,785	N/A	N/A
<b>Total</b>	<b>709,463</b>	<b>745,088</b>	<b>480,158</b>	<b>450,748</b>	<b>6,215</b>	<b>N/A</b>

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*The amounts reported are gross amounts before taxes.*

*(1) Fixed compensation payable in respect of a given year is paid during that year.*

On May 17, 2010, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of the compensation of Serge Weinberg.

For 2010, his fixed compensation was set at an annual rate of 700,000 and was paid on a *pro rata* basis of his chairmanship. Serge Weinberg did not receive any variable compensation, stock options, or performance shares.

Attendance fees relate to the period starting December 15, 2009 and ending May 17, 2010 prior to Serge Weinberg becoming Chairman. Consequently, in line with the Company's compensation policy applicable to the Chairman and the Chief Executive Officer, Serge Weinberg no longer receives any attendance fees as a Director since his appointment as Chairman of the Board.

On March 9, 2011, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of the compensation of Serge Weinberg.

For 2011, his fixed compensation was maintained at an annual rate of 700,000.

He did not receive any variable compensation, stock options, or performance shares. He did not receive attendance fees.

The amount reported for benefits in kind related principally to a company car.

Serge Weinberg does not benefit from the sanofi-aventis top-up pension plan which covers Christopher Viehbacher.

On March 5, 2012, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of the compensation of Serge Weinberg. For 2012, his fixed compensation is maintained at an annual rate of 700,000. He will not receive any variable compensation, stock options, or performance shares. He will not receive attendance fees.

## **Christopher Viehbacher**

Christopher Viehbacher took office as Chief Executive Officer on December 1, 2008.

**Compensation, options and shares awarded to Christopher Viehbacher**

(in euros)	2011	2010	2009
Compensation payable for the year (details provided in the table below)	3,488,287	3,605,729	3,669,973
Value of stock subscription options awarded during the year <sup>(1)</sup>	2,364,000	2,499,750	1,237,500
Value of performance shares awarded during the year <sup>(2)</sup>	1,282,500	887	2,221,700
<b>Total</b>	<b>7,134,787</b>	<b>6,106,366</b>	<b>7,129,173</b>

<sup>(1)</sup> Valued at date of grant using the Black & Scholes method.

<sup>(2)</sup> Valued at date of grant. The value is the difference between the quoted market price of the share on the award date and the dividends to be paid over the next three years. Christopher Viehbacher waived the 2010 allocation.

**Table of Contents****Compensation payable and paid to Christopher Viehbacher**

(in euros)	2011		2010		2009	
	Payable	Paid	Payable	Paid	Payable	Paid
Fixed compensation <sup>(1)</sup>	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000
Variable compensation <sup>(2)</sup>	2,280,000	2,400,000	2,400,000	2,400,000	2,400,000	0
Exceptional compensation <sup>(3)</sup>	0	0	0	0	0	2,200,000
Attendance fees	0	0	0	0	0	0
Benefits in kind	8,287	8,287	5,729	5,729	69,973	69,973
<b>Total</b>	<b>3,488,287</b>	<b>3,608,287</b>	<b>3,605,729</b>	<b>3,605,729</b>	<b>3,669,973</b>	<b>3,469,973</b>

*The amounts reported are gross amounts before taxes.*

*(1) Fixed compensation payable in respect of a given year is paid during that year.*

*(2) Variable compensation in respect of a given year is determined and paid at the start of the following year*

*(3) Exceptional compensation corresponds to a benefit payable upon his starting to hold office.*

At its meeting on March 1, 2010, upon the recommendation of the Compensation Committee, the Board of Directors established the terms of the compensation package for Christopher Viehbacher for the financial year 2010. His fixed compensation remained unchanged at 1,200,000 euros.

His variable compensation with respect to 2010 was based half on the basis of quantitative criteria and half on the basis of qualitative criteria. The quantitative criteria included:

- trends in the our net sales relative to the targets set by us and our competitors,
- trends in the our current operating income (operating income before restructuring, impairment of property, plant and equipment and intangibles, gains/losses on disposals, and litigation) relative to the targets set by us and our competitors, and
- trends in our adjusted earnings per share excluding selected items (which was a non-GAAP financial measures used until the end of 2009).

For reasons of confidentiality, the precise targets set for the quantitative criteria cannot be publicly disclosed. Such criteria were evaluated taking account of the performance of the major global pharmaceutical companies.

The qualitative criteria, based on the strategy determined in 2008, related to leadership and strategic choices, adaptation of our structures to the industry's environment, reconfiguration of our research efforts, commitment in terms of organic and external growth, and the quality of investor communications.

The variable compensation of Christopher Viehbacher could have represented between 0% and 200% of his fixed compensation. In the event of exceptional performance, it could have exceeded 200% of the fixed compensation.



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The Board of Directors, pursuant to the above mentioned criteria and taking into account the performance of the Company and the contribution of Christopher Viehbacher during 2010, fixed his variable compensation for 2010 at 2,400,000, i.e., 200% of the fixed portion of his compensation.

At its meeting on March 9, 2011, upon the recommendation of the Compensation Committee, the Board of Directors established the terms of the compensation package for Christopher Viehbacher for the financial year 2011. His fixed compensation remained unchanged at 1,200,000 euros.

His variable compensation with respect to 2011 was established on the basis of quantitative and qualitative criteria. The criteria have changed and include:

the achievement of financial targets compared to our budget excluding Genzyme;

the development of the growth platforms and the launch of products by research and development;

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the integration of Genzyme;

the organizational and employment policies of the Group.

For reasons of confidentiality, the precise targets set for the quantitative criteria cannot be publicly disclosed. Such criteria were evaluated taking account of the performance of the major global pharmaceutical companies.

The variable compensation structure acts as incentive for the achievement of the financial targets while taking into account sustainable growth centered on continuing operations and increasingly on developing countries and encouraging the human element with an emphasis on the proper integration of Genzyme and a specific focus on employment policies.

In general, the performance criteria apply not only to the variable compensation but also to the vesting of the stock options and performance shares in compliance with our targets, which are ambitious.

The variable compensation of Christopher Viehbacher could have represented between 0% and 200% of his fixed compensation. In the event of exceptional performance, it could have exceeded 200% of the fixed compensation.

The Board of Directors, pursuant to the above mentioned criteria and taking into account the performance of the Company and the contribution of Christopher Viehbacher during 2011, fixed his variable compensation for 2011 at 2,280,000 euros, i.e., 190% of the fixed portion of his compensation. Christopher Viehbacher's 2011 variable compensation is to be paid in 2012.

The amount reported for benefits in kind related to a company car.

At its meeting on March 5, 2012, upon the recommendation of the Compensation Committee, the Board of Directors established the terms of the compensation package for Christopher Viehbacher for the financial year 2012. His fixed compensation for 2012 is fixed at 1,260,000 euros, which represents an increase of 5% compared to the level of fixed compensation set by the Board in 2008 at the time Christopher Viehbacher was recruited.

His variable compensation with respect to 2012 has been established on the basis of quantitative and qualitative criteria. Such criteria include:

the achievement of financial targets compared to our budget;

research and development results;

the development of the Group strategic plan for 2015-2020;

the organization and succession plan for key posts in the Group;

workforce motivation and Group image.

**Stock options awarded to Christopher Viehbacher in 2011**

Origin	Date of Board grant	Nature of the options	Value (in )	Number of options awarded in 2010	Exercise price (in )	Exercise period
sanofi-aventis	03/09/11	Subscription options	2,364,000	300,000	50.48	03/10/2015 03/09/2021

On March 9, 2011, 300,000 share subscription options were awarded to Christopher Viehbacher. In conformity with the AFEP-MEDEF corporate governance code, the entire award is subject both to internal criteria based upon Business Net Income and Return on Assets ( ROA ), and to external criteria based upon Total Shareholder Return ( TSR ) in comparison to a reference set of pharmaceutical companies. These criteria were selected because they align the share-based compensation on the medium-term with the strategy adopted by the Company.

This award is broken down as follows:

- The performance criterion based upon Business Net Income covers 40% of the award. It corresponds to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. If this ratio is less than 90%, the corresponding options will lapse.
- The ROA-based criterion covers 40% of the award. If the target is achieved, all of the corresponding options may be exercised; otherwise such options will all lapse.

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- The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (the dividends), i.e. the two sources of a return on investment in Sanofi shares. Our TSR is compared with a reference set comprised of 12 companies, i.e. Sanofi, Abbott, Astra Zeneca, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, and Bayer. The number of options exercisable depends upon our position in comparison to the TSR for the other companies of this panel.
  
- In addition to the three conditions set forth above, an implicit condition exists: the exercise price, as well as the condition of continued employment.
  
- The performance will be measured over two periods of two financial years.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the quanta for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

Using the Black & Scholes method, each option awarded on March 9, 2011 was valued at 7.88, valuing the total benefit at 2,364,000.

The number of options awarded to Christopher Viehbacher in 2011 represents 0.92% of the global envelope voted by the Shareholders General Meeting held on April 17, 2009 (2.5% of our share capital) and 34.31% of the total award to all beneficiaries on March 9, 2011. The Board of Directors has decided to limit the number of options that could be awarded to Christopher Viehbacher to 10% of the global envelope voted by the Shareholders General Meeting held on May 6, 2011 (1% of our share capital).

**Stock options held by Christopher Viehbacher**

Origin	Date of Board grant	Nature of the options	Value (in )	Number of options awarded	Exercise price (in )	Exercise period
sanofi-aventis	03/02/09	Subscription options	1,237,500	250,000	45.09	03/04/2013 03/01/2019
sanofi-aventis						03/03/2014
	03/01/10	Subscription options	2,499,750	275,000	54.12	02/28/2020
sanofi-aventis		Subscription options				03/10/2015
	03/09/11		2,364,000	300,000	50.48	03/09/2021

On March 5, 2012, 240,000 share subscription options were awarded to Christopher Viehbacher. In conformity with the AFEP-MEDEF corporate governance code, the entire award is subject to both internal criteria based upon Business Net Income and Return on Assets ( ROA ), and to external criteria based upon Total Shareholder Return ( TSR ) in comparison to a reference set of pharmaceutical companies. These criteria were selected because they align the share-based compensation on the medium-term with the strategy adopted by the Company.

This award is broken down as follows:

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- The performance criterion based upon Business Net Income covers 40% of the award. It corresponds to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. The targets have been revised upwards and if the ratio is less than 95%, the corresponding options will lapse.
- The ROA-based criterion covers 40% of the award. The schedule includes a target ROA, performance below which will be penalized by the lapsing of part or all of the options.
- The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (the dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with a reference set comprised of twelve companies, i.e. Sanofi, Abbott, Astra Zeneca, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, and Bayer. The number of options exercisable depends upon our position in comparison to the TSR for the other companies of this panel.

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- In addition to the three conditions set forth above, an implicit condition exists: the exercise price, as well as the condition of continued employment.
- In order to reinforce the medium-term aspects of the share-based compensation, performance will henceforth be measured over three financial years.

The targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

Christopher Viehbacher did not exercise any stock options in 2010 or 2011. None of his stock option awards is currently exercisable.

As of the date of publication of this document, the total number of unexercised options held by Christopher Viehbacher represented 0.08% of the share capital as at December 31, 2011.

**Performance shares awarded to Christopher Viehbacher in 2011**

<b>Origin</b>	<b>Date of Board award</b>	<b>Number of performance shares awarded in 2010</b>	<b>Value (in )</b>	<b>Acquisition date</b>	<b>Availability date</b>
sanofi-aventis	03/09/11	30,000	1,282,500	03/10/2013	03/10/2015

On March 9, 2011, 30,000 performance shares were awarded to Christopher Viehbacher. In conformity with the AFEP-MEDEF corporate governance code, the entire award is subject both to internal criteria based upon Business Net Income and Return on Assets ( ROA ), and to external criteria based upon Total Shareholder Return ( TSR ) in comparison to a reference set of pharmaceutical companies. These criteria were selected because they align the share-based compensation on the medium-term with the strategy adopted by the Company.

This award is broken down as follows:

- The performance criterion based upon Business Net Income covers 40% of the award. It corresponds to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. If this ratio is less than 90%, the corresponding performance shares will lapse.
- The ROA-based criterion covers 40% of the award. If the target is achieved, all of the corresponding performance shares vest; otherwise such performance shares will all lapse.
- The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (the dividends), i.e. the two sources of a return on

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investment in Sanofi shares. Our TSR is compared with a reference set comprised of 12 companies, i.e. Sanofi, Abbott, Astra Zeneca, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, and Bayer. The number of performance shares vested depends upon our position in comparison to the TSR for the other companies of this panel.

- The performance will be measured over a period of two financial years.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the quanta for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

The number of shares awarded to Christopher Viehbacher in 2011 represents 0.23% of the global envelope voted by the Shareholders' General Meeting held on April 17, 2009 (1% of our share capital) and 0.9% of the total award to all beneficiaries on March 9, 2011. The Board of Directors proposes to limit the number of performance shares that could be awarded to Christopher Viehbacher to 5% of the global envelope submitted to the shareholders at the Shareholders' General Meeting to be held on May 4, 2012 (1.2% of our share capital).

**Table of Contents****Performance shares awarded to Christopher Viehbacher**

<b>Origin</b>	<b>Date of Board award</b>	<b>Number of performance shares awarded</b>	<b>Value (in )</b>	<b>Acquisition date</b>	<b>Availability date</b>
sanofi-aventis	03/02/09	65,000	2,221,700	03/03/2011	03/04/2013
sanofi-aventis	03/09/11	30,000	1,282,500	03/10/2013	03/10/2015

On March 2, 2009, in accordance with what had been contemplated on the announcement of his appointment in September 2008, 65,000 performance shares were awarded to Christopher Viehbacher. All of his performance shares were subject to a performance condition. The performance condition, which had to be fulfilled each financial year preceding the vesting of the shares (i.e. 2009 and 2010) was based on the ratio of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales to be at least 18%. On February 24, 2011, the Board of Directors, acting on the recommendation of the Compensation Committee, determined that the conditions to the March 2, 2009 grant had been met for each of the financial years.

Taking into account the number of shares acquired at the outset of his mandate as well as the lock-up obligations applicable to shares obtained on exercise of stock options, or disposition of performance shares, the Board of Directors has decided not to impose any further acquisition of shares out of his own pocket.

Within the context of Share 2010, the Group's global restricted share plan benefiting to each Group employee with at least three months' service, 20 restricted shares were awarded to Christopher Viehbacher on October 27, 2010. This award is not included in the schedule above as Christopher Viehbacher subsequently renounced to this award.

On March 5, 2012, 42,000 performance shares were awarded to Christopher Viehbacher. In conformity with the AFEP-MEDEF corporate governance code, the entire award is subject to both internal criteria based upon Business Net Income and Return on Assets (ROA), and to external criteria based upon Total Shareholder Return (TSR) in comparison to a reference set of pharmaceutical companies. These criteria were selected because they align the share-based compensation on the medium-term with the strategy adopted by the Company.

This award is broken down as follows:

- The performance criterion based upon Business Net Income covers 40% of the award. It corresponds to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. The targets have been revised upwards and if the ratio is less than 95%, the corresponding performance shares will lapse.
- The ROA-based criterion covers 40% of the award. The schedule includes a target ROA, performance below which will be penalized by the lapsing of part or all of the performance shares.
- The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (the dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with a reference set comprised of twelve companies, i.e. Sanofi, Abbott, Astra Zeneca, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, and Bayer. The number of options exercisable depends upon



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our position in comparison to the TSR for the other companies of this panel.

- In order to reinforce the medium-term aspects of the share-based compensation, performance will henceforth be measured over three financial years.

The targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

Concomitantly with the making of the 2012 award, the Board of Directors determined whether to condition these awards on future share purchases. Taking into account the number of shares acquired at the outset of his mandate as well the lock-up obligations applicable to shares obtained on exercise of stock options, or disposition of performance shares as well as spontaneous share purchases by Christopher Viehbacher, the Board of Directors has decided not to impose any further acquisition of shares out of his own pocket.

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As of the date of this annual report, the total number of performance shares awarded to Christopher Viehbacher represents 0.01% of our share capital as of December 31, 2011.

### **Performance shares awarded to Christopher Viehbacher which became available in 2011**

No performance shares awarded to Christopher Viehbacher became available in 2011.

### **Pension arrangements for Christopher Viehbacher**

Christopher Viehbacher is covered by the sanofi-aventis top-up defined benefit pension plan. The plan is offered to all employees of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules, extended to corporate officers, including currently Christopher Viehbacher. This plan was set up on October 1, 2008 as the final stage in the process of harmonizing the status of personnel across the French subsidiaries.

This top-up defined-benefit pension plan is offered to executives (within the meaning of the AGIRC regime *Association Générale des Institutions de Retraite des Cadres*, a confederation of executive pension funds) of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules; the benefit is contingent upon the plan member ending his or her career within the Group. The plan is reserved for executives with at least ten years' service whose annual base compensation has for ten years exceeded four times the French social security ceiling, and is wholly funded by the Company.

Based on the assumptions used in the actuarial valuation of this plan, approximately 480 executives are potentially eligible for this plan, almost all of them active employees.

The top-up pension, which may not exceed 37.50% of final salary, is in the form of a life annuity, and is transferable as a survivor's pension. The annuity is based on the arithmetical average of the three highest years' average annual gross compensation (fixed plus variable) paid during the five years (not necessarily consecutive) preceding final cessation of employment. This reference compensation is capped at 60 times the French social security ceiling (PASS) applicable in the year in which the rights vest. The annuity varies according to length of service (capped at 25 years) and supplements the compulsory industry schemes, subject to a cap on the total pension from all sources equal to 52% of the final level of compensation.

The admission of Christopher Viehbacher to this plan was approved by the Shareholders' General Meeting of April 17, 2009.

### **Commitments in favor of the Chairman and the Chief Executive Officer in office as of December 31, 2011**

#### **Executive director**

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	<b>Contract of employment</b>	<b>Top-up pension plan</b>	<b>Compensation or benefits payable or potentially payable on termination of office</b>	<b>Compensation payable under non-competition clause</b>
Serge Weinberg	No	No	No	No
Christopher Viehbacher	No	Yes	Yes	No

In the event of his removal from office as Chief Executive Officer, Christopher Viehbacher would receive a termination benefit equivalent to 24 months of total compensation on the basis of his fixed compensation effective on the date he ceases to hold office and the last variable compensation received prior to that date, subject to the performance criteria described below.

In accordance with article L. 225-42-1 of the French Commercial Code, payment of the termination benefit would be contingent upon fulfillment of two of the three performance criteria, assessed over the three financial years preceding his ceasing to hold office.

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The three criteria are:

the average of the ratios of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales for each financial year must be at least 15%;

the average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%;

the average of the growth rates for the Group's activities, measured for each financial year in terms of net sales on a comparable basis, must be at least equal to the average of the growth rates of the Pharmaceutical and Vaccines activities of the top 12 global pharmaceutical companies, measured for each financial year in terms of net sales adjusted for the principal effects of exchange rates and changes in scope of consolidation.

The terms for the termination benefit entitlement of Christopher Viehbacher were approved by the Shareholders' Annual General Meeting of April 17, 2009.

Any activation of this termination benefit will be carried out in compliance with the AFEP-MEDEF corporate governance code, *i.e.* only if the departure is non-voluntary and linked to a change in control or strategy.

### **Lock-up period for shares obtained on exercise of stock options or disposition of performance shares by the Chief Executive Officer**

Until he ceases to hold office, the Chief Executive Officer will be required to retain, in the form of Sanofi shares, 50% of any capital gains (net of taxes and social contributions) obtained by the exercise of stock options or upon disposition of performance shares awarded by Sanofi. He must hold these shares in registered.

In conformity with the AFEP-MEDEF corporate governance code, the Board Charter forbids the Chief Executive Officer from contracting any hedging instruments in respect of his own interests, and, in far as Sanofi is aware, no such instruments have been contracted.

### **Compensation and pension payments for Directors other than the Chairman and the Chief Executive Officer**

#### **Attendance fees**

The table below shows amounts paid to each member of the Sanofi Board of Directors in respect of 2010 and 2011, including those whose term of office ended during these years.

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Attendance fees in respect of 2010, the amount of which was set by the Board meeting of February 24, 2011, were be paid in 2011.

Attendance fees in respect of 2011, the amount of which was set by the Board meeting of March 5, 2012, will be paid in 2012.

For 2011, the basic annual attendance fee was set at 15,000, apportioned on a time basis for Directors who assumed or left office during the year.

The variable portion of the fee is linked to actual attendance by Directors in accordance with the principles described below:

Directors resident in France receive 5,000 per Board or Committee meeting attended, except for Audit Committee meetings for which the fee is 7,500 per meeting;

Directors resident outside France receive 7,000 per Board meeting attended, and 7,500 per Committee meeting attended;

the chairman of the Compensation Committee receives 7,500 per Committee meeting;

the chairman of the Audit Committee, who is resident outside France, receives 10,000 per Committee meeting.

The attendance fee payable to a Director who participates by conference call or by videoconference is equivalent to half of the attendance fee received by a French Director who attends in person.

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As an exception, some dual meetings give entitlement to a single attendance fee:

if on the day of a Shareholders' General Meeting, the Board of Directors meets both before and after the Meeting, only one attendance fee is paid for both.

if a Director participates in a meeting of the Compensation Committee and in a meeting of the Appointments and Governance Committee the same day, only one attendance fee is paid for both.

For 2010, as for 2009, a reduction coefficient was applied to this scale in order to keep attendance fees within the total attendance fee entitlement of 1,200,000. The Shareholders' Annual General Meeting of May 6, 2011 approved a proposal to increase the maximum amount of annual attendance fees to 1,500,000.

(in euro)	2011				2010		Pensions paid in 2010	Total theoretical compensation (6)	Total effective compensation (7)
	Attendance fees in respect of 2011 to be paid in 2012		Pensions paid in 2011	Total compensation	Attendance fees in respect of 2010 to be paid in 2011				
	fixed	variable			fixed	Variable			
Uwe Bicker	15,000	71,000		86,000	15,000	98,500		113,500	105,548
Jean-Marc Bruel (1)	0	0		0	5,625	47,500	141,380	194,505	190,923
Robert Castaigne	15,000	103,750		118,750	15,000	107,500		122,500	114,241
Patrick de La Chevadière (2)	0	0		0	7,500	15,000		22,500	20,983
Thierry Desmarest	15,000	75,500		90,000	15,000	92,500		107,500	100,253
Lord Douro	15,000	86,500		101,500	15,000	116,000		131,000	122,168
Jean-René Fourtou	15,000	75,000	1,640,304	1,730,304	15,000	97,500	1,618,818	1,731,318	1,723,733
Claudie Haïgnéré	15,000	65,000		80,000	15,000	65,000		80,000	74,607
Igor Landau	15,000	37,500	2,245,724	2,298,224	15,000	42,500	2,216,308	2,273,808	2,269,931
Suet-Fern Lee (3)	10,000	35,500		45,500	0	0		0	0
Christian Mulliez	15,000	55,000		70,000	15,000	42,500		57,500	53,623
Lindsay Owen-Jones	15,000	42,500		57,500	15,000	62,500		77,500	72,275
Carole Piwnica (4)	15,000	55,000		70,000	0	0		0	0
Klaus Pohle	15,000	135,250		150,250	15,000	143,500		158,500	147,814
Gérard Van Kemmel	15,000	138,750		153,750	15,000	142,500		157,500	146,882
Serge Weinberg (5)	0	0		0	5,625	30,000		35,625	33,223
<b>Total</b>	<b>190,000</b>	<b>975,750</b>	<b>3,886,028</b>	<b>5,051,778</b>	<b>183,750</b>	<b>1,103,000</b>	<b>3,976,506</b>	<b>5,263,256</b>	<b>5,176,504</b>
<b>Total attendance fees (theoretical)</b>	<b>1,165,750</b>				<b>1,286,750</b>				
<b>Total attendance fees (effective)</b>	<b>1,165,750</b>				<b>1,199,997</b>				

(1) Left office May 17, 2010. Compensation from January 1, 2010 to May 17, 2010.

(2) Left office July 1, 2010.

(3) Assumed office May 6, 2011.

(4) Assumed office December 15, 2010.

(5) Assumed office December 16, 2009. Compensation until May 17, 2010.

(6) Before reducing pro rata by 0.93%

(7) After reducing pro rata by 0.93%.

**Pensions**

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The amount recognized in 2011 in respect of corporate pension plans for Directors with current or past executive responsibilities at Sanofi (or companies whose obligations have been assumed by Sanofi) was 4.7 million.

As retirees, Jean-René Fourtou and Igor Landau are covered by the GRCD top-up pension plan instituted in 1977 for senior executives of Rhône-Poulenc. This plan was amended in 1994, 1996, 1999 and 2003, and currently applies to 1 active executive, 4 early retirees and 26 retired executives. At its meeting of February 11, 2008, the Board of Directors decided to close this plan to new entrants. Christopher Viehbacher does not benefit from this top-up pension plan.

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### **Compensation of Senior Management**

The compensation of the other Executive Committee members is established upon the recommendation of the Compensation Committee taking into consideration the practices of major global pharmaceutical companies.

In addition to fixed compensation, they receive variable compensation, which is determined as a function of the trends in the business areas for which the senior managers in question are responsible. Variable compensation generally represents 60% to 110% of their fixed compensation.

In addition to cash compensation, Executive Committee members may be awarded share subscription or purchase options and/or performance shares (see Item 6. Directors, Senior Management and Employees – E. Share Ownership for details of the related plans).

With respect to 2011, the total gross compensation paid and provisioned with respect to members of the Executive Committee (including the Chief Executive Officer) amounted to 13.9 million euros, including 5.7 million euros in fixed compensation.

In 2011, the Board of Directors made significant changes to its share-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except with respect to a limited group of senior managers who may continue to receive options. The members of the Executive Committee are included in this limited group. Furthermore, whoever the beneficiary is, any award of options or performance shares will henceforth be fully subject to the condition of the performance targets being achieved over several financial years as well as a presence condition at the time of the exercise of the option or at delivery of the performance share.

On March 9, 2011, 577,500 share subscription options were awarded to members of the Executive Committee (including 300,000 options awarded to Christopher Viehbacher). The entire award was subject to two internal criteria based on Business Net Income and Return on Assets (ROA).

This award is broken down as follows:

The performance criterion based upon Business Net Income covers 50% of the award. It relates to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. If this ratio is less than 90%, the corresponding options will lapse.

The ROA-based criterion covers 50% of the award. If the target is achieved, all of the corresponding options may be exercised; otherwise such options will all lapse.

In addition to the two conditions set forth above, an implicit condition exists: the exercise price.



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The performance will be measured over two periods of two financial years.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the quanta for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

As of December 31, 2011 a total of 2,552,500 options had been awarded to members of the Executive Committee (existing plans or plans ending in 2011). As of the same date, members of the Executive Committee held 2,452,500 unexercised options. These figures include the unexercised options awarded to Christopher Viehbacher, who is also a member of the Executive Committee.

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The table below summarizes the options awarded to individuals who were members of the Executive Committee at the time of the award. For more information on the characteristics of such options see the table E. Share Ownership Existing Options Plans as of December 31, 2011 below.

Origin	Date of shareholder authorization	Date of Board grant	Grant to Executive Committee Members <sup>(1)</sup>	Start date of exercise period	Expiration date	Purchase price (in 12/31/2011)	Number exercised as of 12/31/2011	Number canceled as of 12/31/2011	Number outstanding
sanofi-aventis	05/31/07	12/13/07	520,000	12/14/11	12/13/17	62.33	0	0	520,000
sanofi-aventis	05/31/07	03/02/09	650,000	03/04/13	03/01/19	45.09	0	50,000	600,000
sanofi-aventis	04/17/09	03/01/10	805,000	03/03/14	02/28/20	54.12	0	50,000	755,000
sanofi-aventis	04/17/09	03/09/11	577,500	03/10/15	03/09/21	50.48	0	0	577,500

<sup>(1)</sup> Comprises the Chief Executive Officer as of the date of grant. Number subject to performance conditions

During the financial year 2011, no option was exercised by the members of the Executive Committee.

On March 9, 2011, 85,500 performance shares (including 30,000 performance shares awarded to Christopher Viehbacher) were awarded to members of the Executive Committee. The entire award was subject to two internal criteria based on Business Net Income and Return on Assets (ROA).

This award is broken down as follows:

The performance criterion based upon Business Net Income covers 50% of the award. It relates to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. If this ratio is less than 90%, the corresponding performance shares will lapse.

The ROA-based criterion covers 50% of the award. If the target is achieved, all of the corresponding performance shares vest, otherwise such performance shares will all lapse.

The performance will be measured over two financial years.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the quanta for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

As of December 31, 2011, the total of 150,500 performance shares had been awarded to members of the Executive Committee (existing plans or plans ending in 2011). As of the same date, 85,500 performance shares were in the process of acquisition. These figures include the performance shares awarded to Christopher Viehbacher, who is also a member of the Executive Committee.

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The table below summarizes the performance shares awarded to individuals who were members of the Executive Committee at the time of the award. For more information on the characteristics of such performance shares see the table E. Share Ownership Existing Restricted Shares Plans as of December 31, 2011 below.

Origin	Date of shareholder authorization	Date of Board Decision	Grant to Executive Committee Members <sup>(1)</sup>	Date of award	Vesting date	Availability date	Number of rights		Number outstanding
							transferred as of 12/31/2011	canceled as of 12/31/2011	
sanofi-aventis	5/31/07	03/02/09	65,000	03/02/09	03/03/11	03/04/13	65,000	0	0
sanofi-aventis	4/17/09	03/09/11	85,500	03/09/11	03/10/13	03/10/15	0	0	85,500

<sup>(1)</sup> Comprises the Chief Executive Officer as of the date of grant. Number subject to performance conditions

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Under French law, Directors may not receive options solely as compensation for service on our Board, and thus our Company may grant options only to those Directors who are also our officers.

Because some of our non-executive Directors were formerly officers or executive officers of our Company or its predecessor companies, some of our non-executive Directors hold Sanofi stock options.

We do not have separate profit-sharing plans for key executives. As employees, they are able to participate in our voluntary and statutory profit-sharing schemes on the same terms as our other employees. These plans are described below under **Employees Profit-sharing schemes**.

The total amount accrued as of December 31, 2011 in respect of corporate pension plans for (i) Directors with current or past executive responsibilities at Sanofi or at companies whose obligations have been assumed by Sanofi and (ii) members of the Executive Committee was 121.2 million, including 9.6 million recognized in the income statement for the year ended December 31, 2011.

This total amount accrued as of December 31, 2011 included 56.2 million for members of the Executive Committee collectively of which 5.9 million were recognized in the income statement for the year ended December 31, 2011.

## **C. Board Practices**

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors providing for benefits upon termination of employment. With respect to Christopher Viehbacher, see also **B. Compensation Christopher Viehbacher** above.

The AFEP-MEDEF corporate governance code requires us to specifically report on the application of its recommendations and, as the case may be, explain the reason why a company would not have applied some of them. Sanofi follows the guidelines contained in the AFEP-MEDEF corporate governance code as amended. Currently our only two departures from this code are:

The limitations to the powers of the Chief Executive Officer are not contained in our Board Charter but in a decision of our Board dated July 28, 2009. The publication and the decision-making process being the same, this departure is technical and has no practical repercussions.

The Committees do not each have their own charter separate from the Board Charter. The Board Charter, which has been adopted by the Board of Directors, gives a global vision of the functioning of the Board and of its committees. Indeed, combining the rules that apply to the Board of Directors and those that apply to its committees creates a single, coherent governing document validated by the entire Board.

During 2011, the Board of Directors met ten times, with an overall attendance rate among Board members over 91%. This attendance rate includes participation by conference call. The attendance rate is particularly high, given that several extraordinary meetings were convened on short notice, largely as a result of the projected acquisition of Genzyme. Nevertheless, participation in Board meetings by conference call remained limited to the extraordinary meetings of the Board, and only affected a limited number of directors.

The following persons attended meetings of the Board of Directors in 2011:

the Directors;

the Secretary to the Board;

five representatives of the employees who attend the Board without voting rights, pursuant to the agreement implemented with the European Works Council signed on February 24, 2005;

and frequent attendance of: the Executive Vice President Chief Financial Officer, the Senior Vice President Legal Affairs and General Counsel, the Senior Vice President and Chief Medical Officer, the President Global Operations, the Vice President of Industrial Affairs, the Vice President of Mergers and Acquisitions the Senior Vice President Animal Health, the Senior Vice President Latin America Region, and the Chairman and Chief Executive Officer of Sanofi Pasteur.

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The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

Around one week prior to each meeting of the Board of Directors, the Directors each receive a file containing the agenda, the minutes for the prior meeting as well as the documentation with respect to the agenda.

The minutes for each meeting are expressly approved at the next meeting of the Board of Directors.

In conformity with the Board Charter, certain subjects, depending upon their area, are examined in advance by the various Committees, which are then presented for a decision by the Board of Directors.

In 2011, the main activities of the Board of Directors related to the following questions:

the projected acquisition of Genzyme, regular updates as to the acquisition and then as to the integration of Genzyme, an update as to Merial and its strategy, a presentation on the Latin America region, an update on the Vaccines strategy,

the review of the individual company and consolidated financial statements for the financial year 2010, the review of the individual company and consolidated financial statements for the first half and the consolidated financial statements for the first three quarters of 2011, as well as the review of the draft press releases and presentations to analysts with respect to the publication of such financial statements and also the press release for the September 6, 2011 investor seminar covering notably distributions to shareholders, the allocation of earnings,

the examination of the documents relating to the management forecasts and the financial arrangements adopted with respect to Group subsidiaries over the financial year 2010, the forecasts for the full year 2011 and the budget for 2012,

both unregulated and regulated agreements, the reclassification of a regulated agreement related to the financing of the acquisition of Genzyme,

the delegation of authority to the Chief Executive Officer to issue bonds, the renewal of the share repurchase program,

reviews of the Management Report, the Chairman's Report and the reports of the statutory auditors,

the recording of the amount of the share capital, the reduction in the share capital through the cancellation of treasury shares and the corresponding amendments to the Articles of Association,

the determination of the 2010 variable compensation for the Chief Executive Officer, certification of the achievement of the performance targets for the performance shares awarded to the Chief Executive Officer in 2009. It should be noted that during the presentation of the report of the Compensation Committee on the compensation of corporate officers, the Board of Directors deliberated without their presence. Accordingly, the Board of Directors in the first place discussed the compensation of the Chairman

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outside of his presence, then in the presence of the Chairman, but without the presence of the Chief Executive Officer, the compensation of the latter was dealt with,

the allocation of the Directors' attendance fees for the year 2010,

the adoption of the share-based compensation schemes comprised of share subscription option plans and restricted shares awards with respect to 2011,

the risk panorama with respect to pharmacovigilance,

the composition of the Board, the reappointment of the Chairman of the Board of Directors, the independence of the Directors, the appointment of a new Director and the appointment of a new member of the Audit Committee,

updating of the Board Charter,

the Company policy on equal pay and opportunities,

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the notice of meeting for the General Meeting of Shareholders and of Holders of Participating Shares (Series issued in 1983, 1984 and 1987 and Series A participating shares issued in 1989), the adoption of the draft resolutions, the report of the Board of Directors on the resolutions, and the special reports on the share subscription options and on the restricted shares awarded,

the transfer of the registered office,

the evaluation of the Board and its Committees.

## **Board Committees**

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist committees. Members of these committees are chosen by the Board from among its members, based on their experience.

The members of these Committees are selected from among the Directors as a function of their experience and are appointed by the Board of Directors.

The Committees are responsible for the preparation of certain items on the agenda of the Board of Directors. The decisions of the Committees are adopted by a simple majority with the chairman of the Committee having a casting vote. Minutes are established and approved by the Committee members.

The Committee chairmen for the Audit Committee, Compensation Committee and the Appointments and Governance Committee are appointed by the Board of Directors.

The chairman of each of such specialist Committee reports to the Board as to the work of the Committee in question, so that the Board is fully informed whenever it adopts a decision.

The Board of Directors thus works in close collaboration with the specialist Committees. Its work is prepared and organized with a continuing concern to ensure that it is both transparent and efficient.

## **Audit Committee**

At December 31, 2011, this Committee was composed of:



**Klaus Pohle**, Chairman;

**Robert Castaigne**;

**Carole Piwnica** (since December 13, 2011);

**Gérard Van Kemmel**.

Carole Piwnica was appointed as a member of the Audit Committee by the Board of Directors during its meeting of December 13, 2011.

During its meeting of December 12, 2011, the Audit Committee examined the experience of Carole Piwnica in her role as a member of various supervisory boards as well as her performance within the Sanofi Board and on the occasions she was invited to attend meetings of the Audit Committee. The Audit Committee concluded that Carole Piwnica has the necessary knowledge and experience in finance and accounting, in particular with respect to IFRS standards and internal controls. On November 2, 2011, the Appointment and Governance Committee examined the independence of its members and concluded that Carole Piwnica was as an independent Director under the AFEP-MEDEF corporate governance code.

Three members of the Audit Committee are classified as independent pursuant to the criteria adopted by the Board of Directors, i.e. Carole Piwnica, Klaus Pohle and Gérard Van Kemmel. In addition, all of the members, including Robert Castaigne, fulfill the conditions required to be classified as independent under the Sarbanes-Oxley Act.

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All four members of the Committee have financial or accounting expertise as a consequence of their education and professional experience. Furthermore, Robert Castaigne, Klaus Pohle and Gérard Van Kemmel are deemed to be financial experts pursuant to the definition in the Sarbanes-Oxley Act and the definition in Article L. 823-19 of the French Commercial Code. See Item 16A. Audit Committee Financial Expert.

The Audit Committee met seven times in 2011, including prior to the meetings of the Board of Directors during which the financial statements were approved. In addition to the statutory auditors, the principal financial officers, the Senior Vice President Audit and Evaluation of Internal Controls as well as other members of senior management of the Group attended meetings of the Audit Committee.

The meetings of the Audit Committee take place at least two days prior to any meetings of the Board of Directors during which the annual or interim financial statements are to be examined.

The members of the Audit Committee have a good attendance record for meetings, with an overall attendance rate among members of 100%.

The statutory auditors attended all of the meetings of the Audit Committee; they presented their views as to the annual and half yearly financial statements at the Committee meetings of February 4, and July 25, 2011, respectively.

In 2011, the main activities of the Audit Committee related to:

the preliminary review of the individual company and consolidated financial statements for the financial year 2010, the review of the individual company and consolidated financial statements for the first half and of the consolidated financial statements for the first three quarters of 2011, as well as a review of the press releases and analysts presentations relating to the publication of such financial statements,

the financial position of the Group, its indebtedness and liquidity,

investigation and evaluation of the internal controls for the financial year 2010, certified by the statutory auditors within the framework of the provisions of Section 404 of the Sarbanes-Oxley Act and an examination of the 2010 Annual Report on Form 20-F,

the principal risks facing the Company, including IT security, global management of risks, the role and tasks of the Risk Committee set-up within the framework of the Executive Committee, the management of financial risks, the approach adopted for the evaluation of internal controls with respect to Genzyme, the tax risks, the provisions related to litigation (meetings of April 26, May 25, July 25, and December 12, 2011),

the conclusions of Group management as to the internal control procedures, the 2010 Management Report and Chairman's Report, including the description of risk factors contained in the French *Document de Référence*,

the acquisition of Genzyme and its financial implications, particularly in terms of valuation and segment information,

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the budget for ancillary and other services as well as the 2011 audit plan and fees of the statutory auditors, the renewal of the mandate of one of the statutory auditors and its deputy,

the expertise in financial and accounting matters of Carole Piwnica with a view to her appointment to the Audit Committee,

its functioning as of the end of the year.

The Committee did not have recourse to external consultants in 2011.

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**Compensation Committee**

At December 31, 2011, this Committee was composed of:

**G rard Van Kemmel**, Chairman;

**Thierry Desmarest**;

**Jean-Ren  Fourtou**;

**Claudie Haigner **;

**Lindsay Owen-Jones**.

Of the five members of the Compensation Committee, three are deemed to be independent.

The Compensation Committee met four times in 2011.

The members of the Compensation Committee have a good attendance record for meetings, with an overall attendance rate among members of 90 %.

In 2011, the main activities of the Compensation Committee related to:

the fixed and variable compensation of the corporate officers and senior management and the establishment of the amount of Directors attendance fees,

the governance chapter of the 2010 *Document de R f rence* which contains the disclosure as to compensation,

the policy for share-based compensation comprised of both share subscription options and performance shares which was discussed at several meetings,

the review of the draft resolutions to be presented to the shareholders in 2011, with respect to the increase in the total amount of Directors attendance fees, the renewal of the delegation of authority granted to the Board to award share subscription or purchase options, as well as the delegation of authority granted to the Board to approve a capital increase reserved for members of the Group s

employee savings scheme,

its functioning as of the end of the year.

The Committee did not have recourse to external consultants in 2011.

When the Committee discusses the compensation policy for members of senior management who are not corporate officers, i.e. the members of the Executive Committee, the Committee invites the members of senior management who are corporate officers to attend.

### **Appointments and Governance Committee**

At December 31, 2011, this Committee was composed of:

**Serge Weinberg**, Chairman;

**Thierry Desmarest**;

**Lord Douro**;

**Jean-René Fourtou**;

**Claudie Haigneré**;

**Lindsay Owen-Jones**;

**Gérard Van Kemmel**.

Of the seven members of the Appointments and Governance Committee, four are deemed to be independent.

The Appointments and Governance Committee met twice in 2011.

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The members of the Appointments and Governance Committee have a good attendance record for meetings, with an overall attendance rate among members of 75 %.

In 2011, the main activities of the Appointments and Governance Committee related to:

the review of the Chairman's Report,

the independence of the Directors,

the changes to the composition of the Board of Directors and its Committees, the target size for the Board of Directors, the proposals with respect to re-election and nomination, the appointment of a fourth member of the Audit Committee,

the proposal for an update to the Board Charter and in particular an increase in the minimum number of shares that each Director is required to hold from 500 to 1,000 shares,

the review of the results of the evaluation of the Board of Directors and its Committees,

The Committee did not have recourse to external consultants in 2011.

## **Strategy Committee**

At December 31, 2011, this Committee was composed of:

**Serge Weinberg**, Chairman;

**Christopher Viehbacher**;

**Uwe Bicker**;

**Thierry Desmarest**;

**Lord Douro**;

**Jean-René Fourtou**;

**Lindsay Owen-Jones.**

Of the seven members of the Strategy Committee, three are deemed to be independent.

The Strategy Committee met twice in 2011, in expanded sessions.

The members of the Strategy Committee have a good attendance record for meetings, with an overall attendance rate among members of 90 %.

The work of the Committee covered, in particular, research and development and the projected acquisition of Genzyme.

The Committee did not have recourse to external consultants in 2011.

**D. Employees**

**Number of Employees**

In 2011, Sanofi employed 113,719 people worldwide, increasing by 12,956 people compared to 2010. This increase is due to the integration of the workforce of various companies acquired by us, mainly Genzyme and Merial. The tables below give a breakdown of employees by geographic area and function as of December 31, 2011.

**Table of Contents****Employees by geographic area**

	As of December 31,					
	2011	%	2010	%	2009	%
Europe	58,339	51.3%	54,815	54%	57,896	55.2%
United States	18,334	16.1%	12,954	12.7%	14,517	13.8%
Other countries	37,046	32.6%	33,806	33.3%	32,454	31%
<b>Total</b>	<b>113,719</b>	<b>100%</b>	<b>101,575</b>	<b>100%</b>	<b>104,867</b>	<b>100%</b>

**Employees by function**

	As of December 31,					
	2011	%	2010	%	2009	%
Sales	32,874	28.9%	32,686	32.2%	34,292	32.7%
Research and Development	18,823	16.6%	16,983	16.7%	19,132	18.3%
Production	44,415	39%	37,504	36.9%	36,849	35.1%
Marketing and Support Functions	17,607	15.5%	14,402	14.2%	14,594	13.9%
<b>Total</b>	<b>113,719</b>	<b>100%</b>	<b>101,575</b>	<b>100%</b>	<b>104,867</b>	<b>100%</b>

**Industrial Relations**

Sanofi's social responsibility is based on the basic principles of respect for people. The Sanofi Social Charter outlines the rights and duties of each Group employee. This Social Charter addresses the major issues to which Sanofi is committed such as equal opportunity for all people without discrimination, health and safety for all, respect for privacy, the right to information and professional training, social protection for employees and their families as well as respect for the principles contained in the Global Compact on labor relations and ILO treaties governing the physical and emotional wellbeing and safety of children.

The Group's social relations are based on respect and dialog. In this spirit, the Company's management and employee representatives meet to exchange views, negotiate, sign agreements and ensure that agreements are being implemented. In 2011, the forums for dialogue with our employees that exist in most of the countries where we operate were kept regularly informed about the Group's operations, various organizational changes and updates on recent acquisitions like Genzyme and Merial.

In Europe, Sanofi's European Works Council (EWC) is made up of 40 members and 40 alternates, representing employees from 27 European Union countries in which we operate. In 2011, EWC members received training about organizational changes.

The EWC met in February, April, May and November 2011 to give the employee representatives regular updates on reorganizations in the Group's various entities (R&D, Industrial Affairs, Commercial Operations, and Support Functions). These developments reflect the adaptation needed for us to adjust and stay competitive internationally, make our research and industrial facilities evolve toward biotechnologies, and also adjust our sales forces based on local regulatory constraints (such as exclusion from reimbursement or price regulation, etc.) and to generic competition for some of our flagship drugs.



In addition, intermediate meetings with the EWC officers provided more regular and timely information of this body based on Group updates. In 2011, a joint working group on employment in Europe was set up and met three times to study threatened and emerging professions in an effort to anticipate trends and communicate about the necessary means required to support employees (training, reconversion, etc.).

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In each European country concerned, negotiations with employee representative bodies were also conducted over the year 2011 to present the changes (sales and support operations with the creation of a multi-country organization in Europe; sale of the Alcorcón site in Spain, etc.) and outline the employee support measures that are the best suited to local situations (internal reconversion, outplacement, voluntary layoff, early retirement, etc.). The objective is to inform employee representatives as early as possible in order to take into account their opinions and proposals.

In November 2011, Sanofi announced a plan to reorganize R&D at a global level by proposing to create integrated research centers in order to develop highly innovative collaborative facilities that are more in line with the current reality in science, medicine and patients' unmet needs.

In Europe, the employee representatives' consultation process has already begun in Germany, Hungary, Italy, in the United Kingdom and the Netherlands.

In the United States, the Boston R&D center will allow us to consolidate discovery and early development activities, while a newly created development center in Bridgewater, NJ, will house clinical development, regulatory affairs and other development platforms.

The France Group Committee Council, made up of 25 members and 25 alternates in addition to labor union representatives, was renewed in 2011 for two years and now includes representatives from newly consolidated companies (Merial, Genzyme). It met in May, June, September and December of 2011. During those meetings, the committee was kept abreast of the operations, financial situation and labor changes in the Group in France, as well as the terms and conditions of the Merial and Genzyme consolidation. A presentation was also offered about changes in the economic environment and the medication reform project.

In 2011, 8 agreements and 5 amendments agreements were discussed with the employee representative bodies. The agreements notably addressed touched on workplace arduousness (agreement on methodology to approach it and agreement on measures to promote prevention and compensation), gender equity, Group-wide implementation of job and skill management planning (GPEC), methods for calculating Group voluntary profit-sharing as well as Sanofi's contribution through matching funds to PEG and PERCO.

Negotiations were also initiated at the end of the year on home working, special leave and time off to care for dependent relatives. These are expected to be finalized in 2012.

Lastly, special agreements were entered into with certain premises of the Group's companies (Sanofi-aventis Research & Development, Sanofi Winthrop Industry, Sanofi Chimie, Sanofi-aventis France, Sanofi Pasteur and the sanofi-aventis group).

In order to further our policy to employ the over-fifties and to prevent psychosocial risks, a number of initiatives were instituted throughout France in 2011:

- Employment of seniors: two years after the implementation of an action plan for the over-fifties in France, persons over 50 years of age made up 6.8% of employees hired in 2011, in accordance with Sanofi's commitment to at least 5%.

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- Concerning the prevention of psychosocial risks, Sanofi continues to implement its initiatives throughout all of its sites in France, sponsored by of a Committee for health and labor created in 2010. The Stress Observatory was put in place at 88% of our sites in 2011 with the goal of detecting situations that require preventative measures to be taken. Lastly, each of the Group's entities in France rolled out initiatives best suited to it (awareness programs for HR, managers, employees, e-Learning, peer meetings, etc.) by involving all actors of occupational health: executive committee, HR, CSR, occupational medicine as well as the Committee for Health, Safety and Working Conditions (CHSCT).

### *Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership*

#### **Profit-sharing Schemes**

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

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### **Voluntary Scheme (*Intéressement des salariés*)**

These are collective schemes that are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

The amount distributed by our French companies during 2011 in respect of voluntary profit-sharing for the year ended December 31, 2010 represented 4.6% of total payroll.

In June 2011, Sanofi entered into a three-year Group-wide agreement, effective from the 2011 financial year, and applicable to all French companies more than 50% owned by Sanofi. Under the agreement, payments under the Group voluntary profit-sharing scheme depend on the most favorable criterion between growth of growth platforms turnover compared to the previous year's turnover (with constant exchange rate and perimeter) and the level of business net income. For each criterion, a schedule allows to determine the percentage of total payroll to be distributed.

### **Statutory Scheme (*Participation des salariés aux résultats de l'entreprise*)**

The scheme is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2011 in respect of the statutory scheme for the year ended December 31, 2010 represented 6.9% of total payroll.

In November 2007, Sanofi entered into a new Group-wide agreement for an indefinite period, covering all the employees of our French companies.

An amendment to this agreement was signed in April 2009, primarily to align the agreement on a change in French legislation (Law 2008-1258 of December 3, 2008) in order to protect against erosion in purchasing power, under which each qualifying employee can elect to receive some or all of his or her profit-sharing bonus without regard to the normally applicable mandatory lock-up period.

### **Distribution Formula**

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

- 60% on the basis of presence during the year; and
- 40% on the basis of annual salary, up to a limit of three times the Social Security ceiling.

#### **Employee Savings Schemes and Collective Retirement Savings Plan**

The employee savings arrangements operated by Sanofi are based on a Group savings scheme (*Plan Epargne Groupe*) and a collective retirement savings plan (*Plan Epargne pour la Retraite Collectif*). These schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes (compulsory investments), and voluntary contributions by employees.

Since June 1, 2008, 75.9% of the employees who benefited from the profit-sharing schemes have opted to invest in the collective retirement savings plan.

In 2011, 117.5 million and 56.9 million were invested in the Group savings scheme and the collective retirement savings plan respectively through the voluntary and statutory schemes for 2010, and through top-up contributions.

#### **Employee Share Ownership**

At December 31, 2011, shares held by employees of Sanofi and of related companies as well as by former employees under Group employee savings schemes amounted to 1.38% of the share capital.

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### **E. Share Ownership**

#### **Senior Management**

Members of the Executive Committee hold shares of our Company amounting in the aggregate to less than 1% of our share capital.

At December 31, 2011, a total of 2,552,500 options had been granted to the members of the Executive Committee (plans existing or closed in 2011) and 2,452,500 unexercised options to subscribe for or to purchase Sanofi shares were held by the members of the Executive Committee. In 2011, no stock option was exercised by members of the Executive Committee.

At December 31, 2011, a total of 150,500 performance shares had been awarded to the members of the Executive Committee (plans existing or closed in 2011) and 85,500 performance shares not yet vested were held by the members of the Executive Committee.

These figures include the options granted to Christopher Viehbacher, who is a member of the Executive Committee. The terms of these options and performance shares are summarized in the tables below.

#### **Existing Option Plans as of December 31, 2011**

As of December 31, 2011, a total of 67,732,064 options were outstanding, including 3,204,077 options to purchase Sanofi shares and 64,527,987 options to subscribe for Sanofi shares. Out of this total, 40,872,339 were immediately exercisable, including 3,204,077 options to purchase shares and 37,668,262 options to subscribe for shares.

The share-based compensation which is composed of share subscription option plans and performance share plans and which aims to align the employees' objectives on those of the shareholders and to reinforce the link between employees and the Group, falls within the powers of the Board of Directors under French law. Stock options (which may be options to subscribe for shares or options to purchase shares) are granted to employees and the Chief Executive Officer by the Board of Directors on the basis of recommendations from the Compensation Committee.

Granting options is a way of recognizing the beneficiary's contribution to the Group's development, and also of securing his or her future commitment to the Group.

For each plan, the Compensation Committee and the Board of Directors assess whether it should take the form of options to subscribe for shares or options to purchase shares, based on criteria that are primarily financial.

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A list of beneficiaries is proposed by the Senior Management to the Compensation Committee, which reviews the list and then submits it to the Board of Directors, which grants the options. The Board of Directors also sets the terms for the exercise of the options (including the exercise price) and the lock-up period. The exercise price never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading days preceding the date of grant by the Board. Stock option plans generally specify a vesting period of four years and a total duration of ten years.

In 2011, the Board of Directors made significant changes to its share-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except with respect to a limited group of senior managers who may continue to receive options. Furthermore, whoever the beneficiary is, any award of options or performance shares will henceforth be fully subject to the condition of the performance targets being achieved over several financial years.

On March 9, 2011, 574,500 share subscription options were awarded to 27 beneficiaries (excluding 300,000 options awarded to Christopher Viehbacher). Each option entitles to the subscription of one share, in the aggregate representing 0.04% of our share capital before dilution.

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This award is broken down as follows:

The performance criterion based upon Business Net Income covers 50% of the award. It relates to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. If this ratio is less than 90%, the corresponding options will lapse.

The ROA-based criterion covers 50% of the award. If the target is achieved, all of the corresponding options may be exercised; otherwise such options will all lapse.

In addition to the two conditions set forth above, an implicit condition exists: the exercise price.

The performance will be measured over two periods of two financial years.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the quanta for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

The percentage of options awarded to Christopher Viehbacher in 2011 represent 0.92% of the global envelope voted by the Shareholders General Meeting held on April 17, 2009 (2.5% of our share capital) and 34.31% of the total award to all beneficiaries on March 9, 2011.

Not all of the employees are able to benefit from the awards of performance shares, but a new agreement on the voluntary scheme (*intéressement des salariés*) was concluded in June 2011 to ensure that all employees have an interest in the performance of the business.

In addition, pursuant to the French Law of July 28, 2011, all of the employees in France of the French subsidiaries of the Group benefited from a profit-sharing bonus amounting to 600 euros in November 2011. In total, Sanofi paid out 17.9 million euros in this regard.

On March 5, 2012, the Board of Directors awarded 574,050 share subscription options to 55 beneficiaries (excluding 240,000 options awarded to Christopher Viehbacher). Each option entitles to the subscription of one share, in the aggregate representing 0.04% of our share capital before dilution.

This award is broken down as follows:

The performance criterion based upon Business Net Income covers 50% of the award. It relates to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. The targets have been revised upwards and if the ratio is less than 95%, the corresponding options will lapse.



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The ROA-based criterion covers 50% of the award. The schedule includes a target ROA, performance below which will be penalized by the lapsing of part or all of the options.

In addition to the two conditions set forth above, an implicit condition exists: the exercise price.

In order to reinforce the medium-term aspects of the share-based compensation, performance will henceforth be measured over three financial years, whatever the form of the share-based compensation.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the quanta for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

**Table of Contents****Share Purchase Option Plans**

Origin	Date of shareholder authorization	Date of Board grant	Number of options initially granted	- to corporate officers <sup>(1)</sup>	- to the 10 employees granted the most options <sup>(2)</sup>	Start date of exercise period	Expiration date	Purchase price (in )	Number exercised as of 12/31/2011	Number canceled as of 12/31/2011	Number outstanding
Synthelabo	6/28/1990	12/15/1993	364,000	130,000	104,000	12/15/1998	12/15/2013	6.36	358,800	5,200	0
Synthelabo	6/28/1990	10/18/1994	330,200	0	200,200	10/18/1999	10/18/2014	6.01	324,500	0	5,700
Synthelabo	6/28/1990	1/12/1996	208,000	0	52,000	1/12/2001	1/12/2016	8.56	193,930	0	14,070
Synthelabo	6/28/1990	4/05/1996	228,800	0	67,600	4/05/2001	4/05/2016	10.85	199,330	0	29,470
Synthelabo	6/28/1990	10/14/1997	262,080	0	165,360	10/14/2002	10/14/2017	19.73	228,638	5,200	28,242
Synthelabo	6/28/1990	6/25/1998	296,400	148,200	117,000	6/26/2003	6/25/2018	28.38	292,300	0	4,100
Synthelabo	6/23/1998	3/30/1999	716,040	0	176,800	3/31/2004	3/30/2019	38.08	446,575	5,720	263,745
Sanofi-Synthelabo	5/18/1999	5/10/2001	2,936,500	145,000	286,000	5/11/2005	5/10/2011	64.50	275,061	2,661,439	0
Sanofi-Synthelabo	5/18/1999	5/22/2002	3,111,850	145,000	268,000	5/23/2006	5/22/2012	69.94	61,000	192,100	2,858,750

<sup>(1)</sup> Comprises the Chairman and Chief Executive Officer, the Chief Executive Officer or equivalent officers as of the date of grant.

<sup>(2)</sup> Employed as of the date of grant.

**Share Subscription Option Plans**

Origin	Date of shareholder authorization	Date of grant	Number of options initially granted	- to corporate officers <sup>(1)</sup>	- to the 10 employees granted the most options <sup>(2)</sup>	Start date of exercise period	Expiration date	Subscription price (in )	Number exercised as of 12/31/2010	Number canceled as of 12/31/2010	Number outstanding
Aventis	5/24/2000	3/29/2001	612,196	0	206,000	3/30/2004	3/29/2011	68.94	28,476	583,720	0
Aventis	5/24/2000	11/07/2001	13,374,051	1,068,261	875,200	11/08/2004	11/07/2011	71.39	880,241	12,493,810	0
Aventis	5/24/2000	3/06/2002	1,173,913	1,173,913	0	3/07/2005	3/06/2012	69.82	0	7	1,173,906
Aventis	5/14/2002	11/12/2002	11,775,414	352,174	741,100	11/13/2005	11/12/2012	51.34	5,133,836	1,970,035	4,671,543
Aventis	5/14/2002	12/02/2003	12,012,414	352,174	715,000	12/03/2006	12/02/2013	40.48	6,146,520	1,751,651	4,114,243
Sanofi-Synthelabo	5/18/1999	12/10/2003	4,217,700	240,000	393,000	12/11/2007	12/10/2013	55.74	191,480	224,750	3,801,470
sanofi-aventis	5/31/2005	5/31/2005	15,228,505	400,000	550,000	6/01/2009	5/31/2015	70.38	6,500	2,025,045	13,196,960
sanofi-aventis	5/31/2005	12/14/2006	11,772,050	450,000	585,000	12/15/2010	12/14/2016	66.91	0	1,061,910	10,710,140
sanofi-aventis	5/31/2007	12/13/2007	11,988,975	325,000	625,000	12/14/2011	12/13/2017	62.33	0	944,545	11,044,430
sanofi-aventis	5/31/2007	03/02/2009	7,736,480	250,000	655,000	03/04/2013	03/01/2019	45.09	995	490,775	7,244,710
sanofi-aventis	4/17/2009	03/01/2010	7,316,355	0	665,000	03/03/2014	28/02/2020	54.12	0	345,270	6,971,085
sanofi-aventis	4/17/2009	03/01/2010	805,000	275,000	805,000	03/03/2014	28/02/2020	54.12	0	50,000	755,000
sanofi-aventis	4/17/2009	03/09/2011	574,500	0	395,000	03/10/2015	03/09/2021	50.48	0	30,000	544,500
sanofi-aventis	4/17/2009	03/09/2011	300,000	300,000	0	03/10/2015	03/09/2021	50.48	0	0	300,000

<sup>(1)</sup> Comprises the Chairman and Chief Executive Officer, the Chief Executive Officer, or equivalent officers as of the date of grant.

<sup>(2)</sup> Employed as of the date of grant.

The main characteristics of our stock options are also described in Note D.15.8 to our consolidated financial statements, included in Item 18 of this annual report.

**Existing Restricted Share Plans as of December 31, 2011**

Since 2009, the Board of Directors has awarded restricted shares to certain employees in order to give them a direct stake in the Company's future and performances via trends in the share price, as a partial substitute for the granting of stock options.

Restricted shares are awarded to employees on the basis of a list submitted to the Compensation Committee. Then this Committee submits this list to the Board of Directors, which awards the shares. The Board of Directors sets the vesting conditions for the award, and any lock-up conditions for the shares.

In 2011, the Board of Directors made significant changes to its share-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except with respect to a limited group of senior managers who may continue to receive options. Furthermore, whoever the beneficiary is, any award of options or performance shares will henceforth be fully subject to the condition of the performance targets being achieved over several financial years.

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On March 9, 2011, the Board of Directors set up two plans:

a French plan awarding 1,366,040 performance shares to 2,376 beneficiaries, subject to a vesting period of two years followed by a lock-up period of two years; and

an international plan awarding 1,934,610 restricted shares to 3,676 beneficiaries, subject to a vesting period of four years.

These plans are broken down as follows:

The performance criterion based upon Business Net Income covers 50% of the award. It relates to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. If this ratio is less than 90%, the corresponding performance shares will lapse.

The ROA-based criterion covers 50% of the award. If the target is achieved, all of the corresponding performance shares vest, otherwise such performance shares will all lapse.

The performance will be measured over two periods of two financial years.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the figures for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

The 2011 awards represent a dilution of 0.25% of our share capital before dilution as of December 31, 2011.

Not all of the employees are able to benefit from the awards of performance shares, but a new agreement on the voluntary scheme (*intéressement des salariés*) was concluded in June 2011 to ensure that all employees have an interest in the performance of the business.

In addition, pursuant to the French Act of July 28, 2011, all of the employees in France of the French subsidiaries of the Group benefited from a profit-sharing bonus amounting to 600 gross in November 2011. In total, Sanofi paid out 17.9 million euros in this regard.

On March 5, 2012, the Board of Directors set up two plans:

a French plan awarding 1,567,100 performance shares to 2,546 beneficiaries, subject to a vesting period of three years followed by a lock-up period of two years; and

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an international plan awarding 3,127,160 restricted shares to 5,042 beneficiaries, subject to a vesting period of four years.

These plans are broken down as follows:

The performance criterion based upon Business Net Income covers 50% of the award. It relates to the ratio, at constant exchange rate, between actual Business Net Income achieved and the Business Net Income specified in the budget. The targets have been revised upwards and if the ratio is less than 95%, the corresponding performance shares will lapse.

The ROA-based criterion covers 50% of the award. The schedule includes a target ROA, performance below which will be penalized by the lapsing of part or all of the performance shares.

In order to reinforce the medium-term aspects of the share-based compensation, performance will henceforth be measured over three financial years.

While for reasons of confidentiality, even though they have been properly established in a precise manner, the quanta for the internal criteria cannot be publicly disclosed, the targets and the level of achievement of the internal criteria will be disclosed publicly at the end of the performance measurement period.

**Table of Contents****Restricted Share Plans**

Origin	Date of shareholder authorization	Date of award	Number of shares initially awarded	- to the 10 employees		Date of award <sup>(3)</sup>	Vesting date	Availability date	Number transferred as of 12/31/2011	Number of rights canceled as of 12/31/2011	Number outstanding
				corporate officers <sup>(1)</sup>	awarded shares <sup>(2)</sup>						
sanofi-aventis	5/31/07	03/02/09	590,060	65,000	13,900	03/02/09	03/03/11	03/04/13	585,782	4,278	0
sanofi-aventis	5/31/07	03/02/09	604,004	0	13,200	03/02/09	03/04/13	03/04/13	356	47,642	556,006
sanofi-aventis	4/17/09	3/01/10	531,725	0	12,600	3/01/10	03/02/12	03/03/14	290	7,280	524,155
sanofi-aventis	4/17/09	3/01/10	699,524	0	16,530	3/01/10	03/02/14	03/03/14	148	47,493	651,883
sanofi-aventis	4/17/09	10/27/10	556,480	20	200	10/27/10	10/27/12	10/28/14	160	15,240	541,080
sanofi-aventis	4/17/09	10/27/10	1,544,860	0	200	10/27/10	10/27/14	10/28/14	320	22,180	1,522,360
sanofi-aventis	4/17/09	03/09/11	1,366,040	0	71,000	03/09/11	03/10/13	03/10/15	200	7,850	1,357,990
sanofi-aventis	4/17/09	03/09/11	1,934,610	0	103,300	03/09/11	03/10/15	03/10/15	0	55,760	1,878,850
sanofi-aventis	4/17/09	03/09/11	30,000	30,000	0	03/09/11	03/10/13	03/10/15	0	0	30,000

<sup>(1)</sup> Comprises the Chief Executive Officer as of the date of grant.

<sup>(2)</sup> Employed as of the date of grant.

<sup>(3)</sup> Subject to vesting conditions.

As of December 31, 2010, a total of 7,062,324 restricted shares were outstanding as the vesting period of each plan had not yet expired.

**Shares Owned by Members of the Board of Directors**

As of December 31, 2011, members of our Board of Directors held in the aggregate 137,106 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 43,196,815 shares held by Total as of such date which may be attributed to Thierry Desmarest (who disclaims beneficial ownership of such shares) and excluding the beneficial ownership of 118,227,307 shares held by L. Oréal as of such date which may be attributed to Lindsay Owen-Jones or Christian Mulliez (who disclaim beneficial ownership of such shares).

**Transactions in Shares by Members of the Board of Directors and comparable persons in 2011**

- On April 13, 2011, Carole Piwnica, Director, bought 500 shares at a price of 51.37 per share;
- On June 16, 2011, Christian Mulliez, Director, acquired 35 shares at a price of 49.60 per share by electing to receive his dividend in shares;
- On June 16, 2011, Christopher Viehbacher, Chief Executive Officer, acquired 442 shares at a price of 49.60 per share by electing to receive his dividend in shares;
- On June 16, 2011, Serge Weinberg, Chairman of the Board of Directors, acquired 66 shares at a price of 49.60 per share by electing to receive his dividend in shares;

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- Elias Zerhouni, President World, Research and Development, bought 10,000 ADR at a price of \$33.40 on August 9, 2011 and 5,000 ADR at a price of \$32.15 on August 10, 2011;
- On August 11, 2011, Christopher Viehbacher, Chief Executive Officer, bought 20,000 shares at a price of 45.01 per share, and
- On November 4, 2011, Gérard Van Kemmel, Director, bought 470 shares at a price of 50.03 per share.

**Table of Contents****Item 7. Major Shareholders and Related Party Transactions****A. Major Shareholders**

The table below shows the ownership of our shares as of January 31, 2012, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the notifications received as disclosed below, except for L. Oréal, no other shareholder currently holds more than 5% of our share capital or voting rights.

	Total number of issued		Number of actual voting rights		Theoretical number of voting rights	
	shares		(excluding own shares) <sup>(3)</sup>		(including own shares) <sup>(4)</sup>	
	Number	%	Number	%	Number	%
<b>L. Oréal</b>	118,227,307	8.82	236,454,614	15.71	236,454,614	15.53
<b>Total</b>	39,225,808	2.93	77,434,821	5.14	77,434,821	5.09
<b>Treasury shares <sup>(1)</sup></b>	17,252,363	1.29	-	-	17,252,363	1.13
<b>Employees <sup>(2)</sup></b>	18,209,756	1.36	35,492,367	2.36	35,492,367	2.33
<b>Public</b>	1,148,084,236	85.61	1,155,698,845	76.79	1,155,698,845	75.92
<b>Total</b>	1,340,999,470	100	1,505,080,647	100	1,522,333,010	100

<sup>(1)</sup> Includes net position of share repurchases under the Group's liquidity contract which amounted to 37,000 as of January 31, 2012. Amounts held under this contract vary over time.

<sup>(2)</sup> Shares held via the Sanofi Group Employee Savings Plan.

<sup>(3)</sup> Based on the total number of voting rights as of January 31, 2012.

<sup>(4)</sup> Based on the total number of voting rights as of January 31, 2012 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des Marchés Financiers (i.e., calculated before suspension of the voting rights of treasury shares).

Our *statuts* (Articles of Association) provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see Item 10. Additional Information B. Memorandum and Articles of Association.

L. Oréal is the only entity known to hold more than 5% of the outstanding Sanofi ordinary shares. This entity reduced its holding from 2007 to 2011 after no significant changes in 2006 and 2005. At year end 2007, its holding was 8.66% of our share capital compared to 8.82% on December 31, 2011.

On April 28, 2011, Total declared that it had passed below the legal threshold of 5% of share capital as a result of its share sales, and held as of the declaration date shares representing 4.99% of our share capital and 8.59% of our voting rights.

In accordance with our *statuts*, shareholders are required to notify us once they have passed the threshold of 1% of our share capital or our voting rights and each time they cross an incremental 1% threshold (see Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages).



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For the year ended December 31, 2011, we were informed that the following share ownership declaration thresholds had been passed:

Amundi declared that, as a result of holdings through its mutual funds (*fonds communs de placement*), it had passed successively above on January 5, 2011 and below on January 6, 2011, the threshold of 3% of our share capital and successively below on May 23, 2011 and above on June 7, 2011, the threshold of 2% of our voting rights and as of its last declarations held 2.98% of our share capital (declaration of January 6, 2011) and 2% of our voting rights (declaration of June 7, 2011).

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Crédit Suisse declared that the Crédit Suisse Group had passed successively above the threshold of 1% of our share capital (declaration of January 28, 2011), and successively above and below the thresholds of 1%, 2% and 3% of our share capital, and as of its last declaration held 0.996% of our share capital (declaration of December 19, 2011).

Dodge & Cox declared that it had passed above the threshold of 3% of our share capital and as of its last declaration held 3.39% of our share capital and 2.97% of our voting rights (declarations of June 21, 2011 and of December 14, 2011).

Franklin Resources declared that it had passed below on September 15, 2011 and above on September 27, 2011, the threshold of 2% of our share capital, and as of its last declaration held 2% of our share capital and 1.75% of our voting rights (declaration of September 27, 2011).

L. Oréal declared that it had passively passed above the threshold of 9% of our share capital, and as of its last declaration held 8.76% of our share capital and 15.23% of our voting rights (declaration of May 31, 2011).

Natixis Asset Management declared that it had passed above the threshold of 2% of our share capital, and as of its last declaration held 2.07% of our share capital (declaration of September 16, 2011).

Total declared that as a result of share sales, it had passed successively below the thresholds of 5% and 4% of our share capital (declarations of April 28, 2011 and September 29, 2011) and the thresholds of 9%, 8%, 7% and 6% of our voting rights (declarations of January 14, 2011, May 26, 2011, September 8, 2011 and December 1, 2011), and as of its last declaration held 3.5% of our share capital and 5.99% of our voting rights (declaration of December 1, 2011).

Since January 1, 2012, we have been informed that one legal threshold had been passed.

On February 16, 2012, Total declared that it had passed below the legal threshold of 5% of our voting rights as a result of its share sales, and as of its last declaration held 2.83% of our share capital and 4.69% of our voting rights. On February 10, 2012, Total confirmed its intent to sell the remainder of its shareholding in Sanofi by the end of 2012.

Moreover since January 1, 2012 we have been informed that the following share ownership declaration thresholds have been passed:

Amundi declared that, as a result of share acquisitions through its mutual funds (*fonds communs de placement*), it had passed above the threshold of 3% of our share capital and as of its last declarations held 3.16% of our share capital (declaration of February 8, 2012).

Caisse des Dépôts et Consignations declared that it had passed below the thresholds of 2% of our share capital and as of its last declaration held 1.99% of our share capital and 1.74% of our voting rights (declaration of January 20, 2012).

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Crédit Suisse declared that the Crédit Suisse Group had passed above and below the threshold of 1% of our share capital, and as of its last declaration held 0.99% of our share capital (declaration of February 17, 2012).

Franklin Resources declared that it had passed below the threshold of 2% of our share capital, and as of its last declaration held 1.99% of our share capital and 1.75% of our voting rights (declaration of February 6, 2012).

Total declared that as a result of share sales, it had passed below the thresholds of 3% and as of its last declaration held 2.98% of our share capital and 5.11% of our voting rights (declaration of January 19, 2012).

Individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the sanofi-aventis Group Employee Savings Plan) hold approximately 5.4% of our share capital. Institutional shareholders (excluding L'Oréal and Total) hold approximately 78.5% of our share capital. Such shareholders are primarily American (28.4%), French (18.3%) and British (12.9%). German institutions

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hold 3.4% of our share capital, Swiss institutions hold 2.2%, institutions from other European countries hold 8% and Canadian institutions hold 1.3% of our share capital. Other international institutional investors (excluding those from Europe and the United States) hold approximately 4.2% of our share capital. In France, our home country, we have 10,711 identified holders of record. In the United States, our host country, we have 57 identified shareholders of record and 12,026 identified ADS holders of record.

(source: a survey conducted by Euroclear France as of December 31, 2011, and internal information).

### ***Shareholders Agreement***

We are unaware of any shareholders agreement currently in force.

### **B. Related Party Transactions**

In the ordinary course of business, we purchase or provide materials, supplies and services from or to numerous companies throughout the world. Members of our Board of Directors are affiliated with some of these companies. We conduct our transactions with such companies on an arm's-length basis and do not consider the amounts involved in such transactions to be material.

On September 17, 2009, Sanofi acquired the interest held by Merck & Co., Inc. (Merck) in Merial Limited (Merial) and Merial has been a wholly-owned subsidiary of Sanofi since that date. As per the terms of the agreement signed on July 29, 2009, Sanofi also had an option, following the closing of the Merck/Schering-Plough merger, to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new Merck and Sanofi. On March 8, 2010, Sanofi exercised its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial. On March 22, 2011, Merck and Sanofi jointly announced the mutual termination of their agreement to form a new animal health joint venture. As a result, Merial and Intervet/Schering-Plough continue to operate as separate businesses. Consequently, the assets and liabilities of Merial, which previously were classified in Sanofi's balance sheet as assets or liabilities held for sale or exchange, have been reclassified to the relevant balance sheet line items with no restatement of comparative periods. At the same time, results from the Merial business were included in continuing operations for all the periods reported (for more information on these and other impacts of the termination of the agreement on Sanofi's financial statements, see Notes D.2 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report).

On October 2, 2010, in order to fund a significant part of its proposed acquisition of Genzyme Corporation, Sanofi executed a Facilities Agreement (the Facilities Agreement, described at Item 10. Additional Information C. Material Contracts herein) with J.P. Morgan plc, Société Générale Corporate & Investment Banking and BNP Paribas for unsecured term loan facilities of up to U.S.\$15,000,000,000. Because Robert Castaigne serves on the boards of both Société Générale and Sanofi, Sanofi submitted the Facilities Agreement and certain non-material ancillary agreements, as well as a subsequent amendment, to the prior approval of its Board of Directors with Robert Castaigne abstaining from the vote. In April 2011, U.S.\$4,000,000,000 were borrowed by Sanofi under the Facilities Agreement to fund partly the acquisition of Genzyme and these amounts were fully reimbursed during the course of 2011. The Facilities Agreement expired as a consequence of such reimbursement.

In addition, cash management agreements exist between Sanofi and certain of its subsidiaries.

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Other than these agreements, during 2011 and through the date of this annual report, we have not been involved in, and we do not currently anticipate becoming involved in, any transactions with related parties that are material to us or to any of our related parties or that are unusual in their nature or conditions. We have not made any outstanding loans to or for the benefit of:

enterprises that, directly or indirectly, control or are controlled by, or are under common control with us;

enterprises or associates in which we have significant influence or that have significant influence over us;

shareholders beneficially owning a 10.0% or greater interest in our voting power;

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any member of our Executive Committee or Board of Directors or close members of such individuals' families; or

enterprises in which persons described above own, directly or indirectly, a substantial interest in the voting power or over which persons described above are able to exert significant influence.

**C. Interests of Experts and Counsel**

N/A

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### **Item 8. Financial Information**

#### ***A. Consolidated Financial Statements and Other Financial Information***

Our consolidated financial statements as of and for the years ended December 31, 2011, 2010, and 2009 are included in this annual report at Item 18. Financial Statements.

#### **Dividends on Ordinary Shares**

We paid annual dividends for the years ended December 31, 2006, 2007, 2008, 2009 and 2010 and our shareholders will be asked to approve the payment of an annual dividend of 2.65 per share for the 2011 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on May 15, 2012.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2011 dividend equates to a distribution of 39.8% of our business earnings per share. For information on the non-GAAP financial measure, business earnings per share, see Item 5. Operating and Financial Review and Prospects Business Net Income.

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2007, 2008, 2009 and 2010 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2011 fiscal year at our May 4, 2012 shareholders' meeting.

	2011 <sup>(1)</sup>	2010	2009	2008	2007
Net Dividend per Share (in €)	2.65	2.50	2.40	2.20	2.07
Net Dividend per Share (in \$) <sup>(2)</sup>	3.43	3.34	3.46	3.06	3.02

*(1) Proposal, subject to shareholder approval.*

*(2) Based on the relevant year-end exchange rate.*

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

#### **Annual Payments on Participating Share Series A (PSSA)**

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The table below sets forth, for the years indicated, the amount of dividends paid per PSSA (see Item 9. The Offer and Listing for further detail). In the United States, the PSSAs exist in the form of American Depositary Shares issued by The Bank of New York Mellon, formerly known as The Bank of New York, as depository, each representing one-quarter of a PSSA ( PSSA-ADSs ). The PSSAs are generally entitled to receive an annual payment determined according to a specific formula and subject to certain conditions.

The annual payments on the PSSAs are equal to the sum of a fixed portion ( 1.14 per PSSA) and a variable portion equal to the greater of 704% of the dividend per ordinary share or 150% of an amount calculated pursuant to a formula which takes into account changes in consolidated sales and consolidated net income.

Such amounts have been translated in each case into U.S. dollars and adjusted for the one-to-four ratio of PSSAs to PSSA-ADSs. Annual payments paid to holders of PSSA-ADSs will generally be exempt from French withholding tax.

In 2011, the annual payment per PSSA in respect of 2010 was equal to 18.7521.

	2010	2009	2008	2007	2006
Annual payment per PSSA	18.7521	18.0477	16.6390	15.7234	13.4695
Annual payment per PSSA-ADS	\$ 6.6303	\$ 5.7708	\$ 6.0204	\$ 5.8550	\$ 4.5877



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**Table of Contents****Information on Legal or Arbitration Proceedings**

This Item 8 incorporates by reference the disclosures found at Note D.22 to the consolidated financial statements found at Item 18 of this annual report; material updates thereto as of the date of this annual report are found below under the heading **Updates to Note D.22**.

Sanofi and its affiliates are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As a result, the Group may become subject to substantial liabilities that may not be covered by insurance and could affect our business and reputation. While we do not currently believe that any of these legal proceedings will have a material adverse effect on our financial position, litigation is inherently unpredictable. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on results of operations, cash flows and/or our reputation.

**Patents***Plavix® Patent Litigation*

*United States.* Sanofi and Bristol-Myers Squibb sought damages from Apotex, in reparation of harm caused by that company's at risk marketing and sale of an infringing generic version of Plavix® in 2006. In October 2010, the U.S. District Court awarded Sanofi and Bristol-Myers Squibb damages in the amount of U.S.\$442,209,362, plus U.S.\$107,930,857 in pre-judgment interest, as well as costs and post-judgment interest as set by statute. Apotex secured the amount of the award by cash deposit and filed a notice of appeal. On October 18, 2011, the U.S. Court of Appeals for the Federal Circuit upheld the U.S. District Court ruling regarding the amount of damages but did not uphold the District Court decision regarding the pre-judgment interest. Sanofi's and Bristol-Myers Squibb's petition for rehearing en banc with respect to the Court of Appeals decision concerning pre-judgment interest was denied on January 13, 2012. The order of payment of the damages was issued in February 2012.

*Australia.* On August 17, 2007, GenRX, a subsidiary of Apotex obtained registration of a generic clopidogrel bisulfate product on the Australian Register of Therapeutic Goods and sent notice to Sanofi that it had in parallel applied to the Federal Court of Australia for an order revoking the Australian enantiomer patent claiming clopidogrel salts. On September 21, 2007, Sanofi obtained a preliminary injunction from the Federal Court preventing commercial launch of this generic clopidogrel bisulfate product until judgment on the substantive issues of patent validity and infringement. In February 2008, Spirit Pharmaceuticals Pty. Ltd. also introduced a nullity action against the Australian enantiomer patent. The Spirit proceeding was consolidated with the Apotex proceeding.

On August 12, 2008, the Australian Federal Court confirmed that the claim directed to clopidogrel bisulfate was valid and infringed. Claims covering the hydrochloride, hydrobromide and taurocholate salts also were found valid. However claim 1 of the patent directed to clopidogrel and its pharmaceutical salts was found to be invalid. All parties appealed. In September 2009, the Full Federal Court of Australia held the Australian patent covering clopidogrel to be invalid. Sanofi filed an appeal with the Supreme Court in November 2009. The security bond posted by Sanofi in connection with the preliminary injunction obtained in 2007 was subsequently increased from Australian \$40 million to Australian \$204 million (160 million as of December 31, 2011). In March 2010, the Supreme Court refused special leave to appeal. Apotex is now seeking damages for having been subject to an injunction. The case is in the early stages.

*Canada.* On April 22, 2009, Apotex filed an impeachment action against Sanofi in the Federal Court of Canada alleging the invalidity of Sanofi's Canadian Patent No. 1,336,777 (the 777 Patent) claiming clopidogrel bisulfate. On June 8, 2009, Sanofi filed its defense to the impeachment action and filed a suit against Apotex for infringement of the 777 Patent. The actions were combined and the trial was completed in June 2011. In December 2011, the Federal Court issued a decision that the 777 Patent is invalid, and subsequently generic companies entered the market with generic clopidogrel products. Sanofi is appealing this decision to the Federal Court of Appeal.

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*Apotex Settlement Claim*

On November 13, 2008, Apotex filed a complaint before a state court in New Jersey against Sanofi and Bristol-Myers Squibb claiming the payment of a U.S.\$60 million break-up fee, pursuant to the terms of the initial settlement agreement of March 2006 relating to the U.S. Plavix® patent litigation. On April 8, 2011, the New Jersey state court granted Sanofi and Bristol-Myers Squibb's motion for summary judgment. Apotex filed an appeal to the Superior Court of New Jersey, Appellate Division. Oral argument is expected in the second quarter of 2012. In January 2011, Apotex filed a lawsuit in Florida State Court, Broward County, alleging breach of contract relating to the parties' May 2006 proposed settlement agreement. Discovery is ongoing.

*Allegra® Patent Litigation*

*Japan.* On November 8, 2010, Takada Seiyaku Co. Ltd. filed a patent invalidation action at the Japan patent office (JPO) against Japan patent nos. 3041954 and 3037697. Subsequently, on January 11, 2011, Sawai Pharmaceutical Co., Ltd filed a patent invalidation at the Japan patent office against the same patents. Sanofi is the exclusive licensee of these patents, which are set to expire in March 2014, but have obtained a patent term extension for use in treating dermatitis until September 2015. On December 9, 2011, the JPO found the patents invalid and Sanofi subsequently appealed on December 15, 2011 to the Intellectual Property High Court. The appeal is currently pending. On January 17, 2012, Sawai Pharmaceutical Co., Ltd filed a declaratory judgment action at the Tokyo District Court seeking the Court to find Japan Patent Nos. 3041954 and 3037697 invalid. This declaratory judgment action is currently pending.

*Eloxatin® (oxaliplatin) Patent Litigation*

*United States.* Starting in February 2007, over a dozen ANDA certifications relating to Eloxatin® (oxaliplatin) solution and/or lyophilized products were filed contesting part or all of the Orange Book patents under Paragraph IV. Each of the generic manufacturers was sued for infringement of one or more of the Orange-Book listed patents before the U.S. District Court for the District of New Jersey. U.S. regulatory data exclusivity expired in February 2008.

In June 2009, the U.S. District Court for the District of New Jersey granted a summary judgment motion in favor of certain generic manufacturers. The District Court held that the generic oxaliplatin products that would be introduced by these generic challengers would not infringe the U.S. Patent No. 5,338,874 (the 874 Patent). While Sanofi obtained appellate reversal of the District Court's judgment, a number of generic oxaliplatin products were launched at risk in the United States over the second half of 2009. Sanofi had been unsuccessful in obtaining injunctive relief. On December 2, 2009, the court asked all the parties to consider settlement.

By April 2010, Sanofi and Debiopharm, licensor of the patents rights concerned, signed settlement agreements with all but one of the generic manufacturers, Sun Pharmaceuticals, thus resolving the litigation over certain formulations of Eloxatin® (oxaliplatin) in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Columbia.

Under the terms of the settlement agreements, the generic manufacturers would cease selling their unauthorized generic oxaliplatin products in the U.S. starting from June 30, 2010, to August 9, 2012, at which time the generic manufacturers would be authorized to sell generic oxaliplatin products under a license, before expiry of the patents at issue. The settlement provisions, including the market exit and re-entry dates noted above, are subject to contingencies. The settlement agreements are subject to review by the Federal Trade Commission, the U.S. Department of

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Justice and the Attorney General for the State of Michigan.

In addition, the court decided that the above-described obligation to cease selling unauthorized generic oxaliplatin in the U.S. market also applied to Sun Pharmaceuticals and issued an injunction against Sun Pharmaceuticals. Sun Pharmaceuticals appealed that decision. On December 22, 2010, the Court of Appeals for the Federal Circuit ruled in favor of Sun Pharmaceuticals, by vacating the U.S. District Court of New Jersey decision and entering an injunction which required Sun Pharmaceuticals to cease selling its at risk generic product on June 30, 2010. The Federal Circuit then remanded the case to the District Court.

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In February 2011, the U.S. District Court for the District of New Jersey granted Sanofi's request for a preliminary injunction prohibiting Sun Pharmaceuticals from launching an unauthorized generic product. On September 15, 2011, the U.S. District Court for the District of New Jersey ruled in favor of Sanofi, requiring that Sun's unauthorized generic oxaliplatin remain off the U.S. market until August 9, 2012, pursuant to the April 2010 consent judgment. On October 12, 2011, Sun filed a Notice of Appeal to the Federal Circuit seeking to overturn the District Court's judgment. That appeal is pending.

In a related matter, on June 17, 2011, Sanofi filed suit against Sun Pharmaceuticals in the U.S. District Court for the District of New Jersey in response to Sun's application filed with the FDA seeking marketing approval for a new solution formulation of a generic oxaliplatin product. On December 5, 2011, Sanofi and Sun stipulated that Sun's proposed generic solution product would be governed by the settlement and license agreements governing Sun's other proposed generic oxaliplatin product, which enjoin Sun from marketing either product before August 9, 2012.

### *Synvisc One® Patent Litigation*

In April 2011, Genzyme filed suit in the U.S. District Court for the District of Massachusetts against generic manufacturers Seikagaku Corporation (Seikagaku), Zimmer Holdings, Inc., Zimmer, Inc. and Zimmer U.S., Inc. (collectively, Zimmer) for the infringement of U.S. Patent No. 5,399,351 (the 351 patent) and U.S. Patent No. 7,931,030 (the 030 patent), upon Seikagaku's and Zimmer's launch of generic versions of Synvisc-One® in the United States.

On October 3, 2011, the U.S. District Court granted Genzyme's motion for a temporary restraining order preventing Seikagaku and Zimmer from marketing their generic versions of Synvisc-One® for the remainder of the year 2011.

On December 30, 2011, the U.S. District Court further granted, in part, Genzyme's Motion for a preliminary injunction, enjoining Seikagaku and Zimmer from selling generic versions of Synvisc-One®, pending a decision in the infringement action, except on limited and specific pricing conditions. Full trial on the merits is scheduled to begin in the second quarter of 2012.

### *Glossary of Patent Terminology*

A number of technical terms which may be used above in Item 8 are defined below for the convenience of the reader.

*ANDA or Abbreviated New Drug Application (United States):* An application by a drug manufacturer to receive authority from the U.S. FDA to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties (bioequivalence) as the original approved product. As a result of data exclusivity, the ANDA may be filed only several years after the initial market authorization of the original product.

*Paragraph III and Paragraph IV Certifications:* ANDAs relating to approved products for which a patent has been listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, must specify whether final FDA approval of the ANDA is sought only *after* expiration of the listed patent(s) (this is known as a Paragraph III certification under the Hatch-Waxman Act)

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or whether final FDA approval is sought *prior* to expiration of one or more listed patents (a Paragraph IV certification). ANDAs including a Paragraph IV certification may be subject to the 30-Month Stay defined below.

*Section 505(b)(2) application:* A section 505(b)(2) application may be used to seek FDA approval for, among other things, combination products, different salts of listed drugs, products that do not demonstrate bioequivalence to a listed drug and over-the-counter versions of prescription drugs.

*Summary judgment:* A judgment granted on a claim or defense about which there is no genuine issue of material fact and upon which the movant is entitled to prevail as a matter of law. This procedural device allows the speedy disposition of a controversy without the need for trial.

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*30-Month Stay (United States):* If patent claims cover a product listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, and are owned by or licensed to the manufacturer of the original version, the FDA is barred from granting a final approval to an ANDA during the 30 months following the patent challenge, unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable. FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, which may continue to be litigated in the courts.

## **Regulatory Claims**

### *Lovenox® Regulatory Litigation*

In July 2010, Sanofi learned that the Food and Drug Administration (FDA) had approved a generic enoxaparin ANDA filed by Sandoz. Sanofi subsequently filed suit against the FDA in the U.S. District Court for the District of Columbia and requested preliminary injunctive relief against the FDA. In August 2010, the U.S. District Court denied this request. As a result of this ruling, the generic version of enoxaparin can continue to be marketed in the United States. On February 7, 2012, the Court ruled in favor of the FDA regarding the approval of the Sandoz enoxaparin ANDA.

## **Government Investigations Pricing and Marketing Practices**

Subsidiaries of Sanofi are subject from time to time to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products. For example, Sanofi is cooperating with the U.S. Department of Justice in its respective investigations into the promotion of Sculptra®, Septrafilm®, and Hyalgan®. In France, Sanofi is involved in an investigation by the Antitrust Authority (*Autorité de la Concurrence*) concerning allegations brought by Teva Santé that Sanofi's communications and promotional practices foreclosed the entry on the market of Plavix® generics. In Germany, following a criminal complaint filed by Sanofi against one of its distributors, a criminal investigation was initiated against four Sanofi employees in connection with the alleged sale in Germany of medications originally destined for humanitarian aid outside of the European Union.

## **Updates to Note D.22**

N/A

## ***B. Significant Changes***

N/A





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We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank, N.A..

Our shares trade on Compartment A of NYSE Euronext Paris, or Euronext Paris, and our ADSs trade on the New York Stock Exchange, or NYSE.

In April 2011, in connection with our acquisition of Genzyme, we issued contingent value rights ( CVRs ) under a CVR agreement entered into by and between us and the American Stock Transfer & Trust Company, LLC, as trustee (see Item 10.C. Material Contracts – The Contingent Value Rights Agreement). Our CVRs trade on the NASDAQ Global Market.

**Trading History**

The table below sets forth, for the periods indicated, the reported high and low market prices of our shares on Euronext Paris and our ADSs on the NYSE (source: Bloomberg).

Calendar period	Shares, as traded on		ADSs, as traded on the	
	Euronext Paris		NYSE	
	High	Low	High	Low
	(price per share in €)		(price per ADS in \$)	
<b>Monthly</b>				
February 2012	56.91	54.86	38.04	36.31
January 2012	57.42	54.89	37.58	34.92
December 2011	56.75	51.14	36.85	33.64
November 2011	52.51	47.00	35.40	31.61
October 2011	53.53	47.95	37.66	31.63
September 2011	51.90	45.52	37.07	31.00
August 2011	54.75	42.85	39.04	30.98
<b>2011</b>				
First quarter	52.23	46.04	36.29	31.45
Second quarter	56.50	49.64	40.75	35.34
Third quarter	56.82	42.85	40.58	30.98
Fourth quarter	56.75	47.00	37.66	31.61
Full Year	56.82	42.85	40.75	30.98
<b>2010</b>				
First quarter	58.90	51.68	41.59	34.90
Second quarter	55.85	45.21	37.72	28.01

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Third quarter	50.90	44.01	34.10	28.03
Fourth quarter	51.41	46.23	36.31	30.05
Full Year	58.90	44.01	41.59	28.01
<b>2009</b>				
Full Year	56.78	38.43	40.80	24.59
<b>2008</b>				
Full Year	66.90	36.055	49.04	23.95
<b>2007</b>				
Full Year	71.95	56.20	48.30	37.90

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Fluctuations in the exchange rate between the euro and the U.S. dollar will affect any comparisons of euro share prices and U.S. ADS prices.

### ***B. Plan of Distribution***

N/A

### ***C. Markets***

#### **Shares and ADSs**

Our shares are listed on Euronext Paris under the symbol `SAN` and our ADSs are listed on the NYSE under the symbol `SNY`.

As of the date of this annual report, our shares are included in a large number of indices, including the CAC 40 Index, the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris market. The CAC 40 Index indicates trends in the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones EuroSTOXX 50, the Dow Jones STOXX 50, the FTS Eurofirst 100, the FTS Eurofirst 80 and the MSCI Pan-Euro Index, among other indices.

#### **CVRs**

Our CVRs trade on the NASDAQ Global Market under the symbol `GCVRZ`.

#### **Participating Shares Series A**

In accordance with its prior intentions and in the view of the limited number of registered holders of Participating Shares Series A which was reported to Sanofi to amount to 7, as of December 13, 2011, the Company filed on December 16, 2011 a Form 15 to terminate the registration of the Participating Shares Series A. Upon such filing, the Company's duty to file reports with the SEC with respect to such Participating Shares Series A ceased.

#### **Trading by Sanofi in our own Shares**

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Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at Item 10. Additional Information B. Memorandum and Articles of Association Trading in Our Own Shares.

### *D. Selling Shareholders*

N/A

### *E. Dilution*

N/A

### *F. Expenses of the Issue*

N/A

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**Item 10. Additional Information**

***A. Share Capital***

N/A

***B. Memorandum and Articles of Association***

**General**

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our *statuts*, an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our *statuts* relating to our Board of Directors and statutory auditors, see Item 6. Directors, Senior Management and Employees. You may obtain copies of our *statuts* in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our *statuts* specify that our corporate affairs are governed by:

applicable laws and regulations (in particular, Title II of the French Commercial Code); and

the *statuts* themselves.

Article 3 of our *statuts* specifies that the Company's corporate purpose, in France and abroad, is:

acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;

in the following areas:

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purchase and sale of all raw materials and products necessary for these activities;

research, study and development of new products, techniques and processes;

manufacture and sale of all chemical, biological, dietary and hygienic products;

obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;

operating directly or indirectly, purchasing, and transferring for free or for consideration pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;

obtaining, operating, holding and granting all licenses;

within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;

and, more generally:

all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities or having any other purposes likely to encourage or develop the Company's activities.

### **Directors**

#### ***Transactions in Which Directors Are Materially Interested***

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our

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business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefit or any other advantage as a result of the termination or change in their offices or following such termination or change.

In addition, except with respect to any non-compete indemnity or certain pension benefits, any such termination package, (i) must be authorized by our shareholders through the adoption of a separate general shareholders meeting resolution for each such beneficiary, which authorization must be renewed at each renewal of such beneficiary's mandate, and (ii) cannot be paid to such beneficiary unless (a) the Board of Directors decides that such beneficiary has satisfied certain conditions, linked to such beneficiary's performance measured by our Company's performance, that must have been defined by the Board of Directors when granting such package, and (b) such decision is publicly disclosed.

### ***Directors Compensation***

The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined at the Shareholders' Ordinary General Meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at Transactions in Which Directors Are Materially Interested. The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also Item 6. Directors, Senior Management and Employees.

### ***Board of Directors Borrowing Powers***

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the Shareholders' General Meeting. There are currently no limits imposed on the amounts of loans or borrowings that the Board may approve.

### ***Directors Age Limits***

For a description of the provisions of our *statuts* relating to age limits applicable to our Directors, see Item 6. Directors, Senior Management and Employees.

### ***Directors Share Ownership Requirements***

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Pursuant to the Board Charter, our Directors are required to hold at least 1,000 shares during the term of their appointment.

### Share Capital

As of December 31, 2011, our share capital amounted to 2,681,837,622, divided into 1,340,918,811 outstanding shares with a par value of 2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 17,225,803 shares (or 1.28% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2011, the carrying amount of such shares was 933 million.

At an extraordinary general meeting held on May 6, 2011, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights, by an aggregate maximum nominal amount of 1.3 billion. See Changes in Share Capital Increases in Share Capital, below.



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The maximum total amount of authorized but unissued shares as of December 31, 2011 was 231.6 million, reflecting the unused part of the April 17, 2009 and May 6, 2011 shareholder authorizations to issue shares without preemptive rights, outstanding options to subscribe for shares, and awards of shares.

### **Stock Options**

#### ***Types of Stock Options***

We have two types of stock options outstanding: options to subscribe for shares (*options de souscription d'actions*) and options to purchase shares (*options d'achat d'actions*). Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the grant of the options to purchase in order to provide the option holder with shares upon exercise. Following the merger of Aventis with and into sanofi-aventis (which became Sanofi on May 2011), all previously granted options for the shares of Aventis were converted into options for our shares.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on the amount of our equity share capital.

#### ***Stock Option Plans***

Our combined general meeting held on May 6, 2011 authorized our Board of Directors for a period of 26 months to grant, on one or more occasions, options to subscribe for shares and options to purchase shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Article L. 225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 1% of the share capital as of the date of the decision by the Board of Directors to grant such options.

The Board of Directors sets the exercise price of options to subscribe for shares and options to purchase shares. However, the exercise price never incorporates a discount and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board of Directors.

Stock option plans generally provide for a lock-up period of four years and have a duration of ten years.

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Under such authorization the shareholders expressly waive, in favor of the grantees of options to subscribe for shares, of their preemptive rights in respect of shares that are to be issued as and when options are exercised.

The Board of Directors is granted full power to implement this authorization and to set the terms and conditions on which options are granted and the arrangements with respect to the dividend entitlement of the shares.

See Item 6. Directors, Senior Management and Employees E. Share Ownership for a description of our option plans currently in force.

### **Awards of Shares**

Our combined general meeting held on April 17, 2009 authorized our Board of Directors for a period of 38 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Articles L. 225-197-1 *et seq.* of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1% of the share capital as of the date of the decision by the Board of Directors to allot such shares.

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The authorization provides that allotment of shares to the allottees will become irrevocable either (i) at the end of a minimum vesting period of two years, in which case the allottees will also be required to retain their shares for a minimum period of two years from the irrevocable allotment thereof, or (ii) after a minimum vesting period of four years, in which case allottees may not be subject to any minimum retention period.

In the case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares vest.

The Board of Directors sets the terms on which restricted shares are granted and the arrangements with respect to the dividend entitlement of the shares.

See Item 6. Directors, Senior Management and Employees E. Share Ownership for a description of our restricted shares plans currently in force.

## **Changes in Share Capital in 2011**

See Note D.15.1. to our consolidated financial statements included at Item 18 of this annual report.

## **Voting Rights**

In general, each shareholder is entitled to one vote per share at any shareholders' general meeting. Our *statuts* do not provide for cumulative voting rights. However, our *statuts* provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. The double voting rights cease automatically for any share converted into bearer form or transferred from one owner to another, subject to certain exceptions permitted by law.

As of December 31, 2011, there were 183,197,929 shares that were entitled to double voting rights, representing 13.66% of our total share capital, approximately 24.31% of our voting rights held by holders other than us and our subsidiaries, and 24.04% of our total voting rights.

Double voting rights are not taken into account in determining whether a quorum exists.

Under the French Commercial Code, treasury shares or shares held by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

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Our *statuts* allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our *statuts* allow us to request information regarding beneficial ownership directly from such person. See B. Memorandum and Articles of Association – Form, Holding and Transfer of Shares, below.

Our *statuts* provide that Board members are elected on a rolling basis for a maximum tenure of four years.

### **Shareholders Agreement**

We are not aware of any shareholder s agreement currently in force concerning our shares.

### **Shareholders Meetings**

#### ***General***

In accordance with the provisions of the French Commercial Code, there are three types of shareholders meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

electing, replacing and removing directors;

appointing independent auditors;

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approving the annual financial statements;

declaring dividends or authorizing dividends to be paid in shares, provided the *statuts* contain a provision to that effect; and

approving share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our *statuts*, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

changing our Company's name or corporate purpose;

increasing or decreasing our share capital;

creating a new class of equity securities;

authorizing the issuance of securities giving access to our share capital or giving the right to receive debt instruments;

establishing any other rights to equity securities;

selling or transferring substantially all of our assets; and

the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

***Annual Ordinary Meetings***

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders' meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The Board of Directors may also convene an ordinary or extraordinary general shareholders' meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders' meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders' meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders' meeting:

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one or several shareholders holding at least 5% of our share capital;

duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;

the works council in cases of urgency; or

any interested party in cases of urgency.

### ***Notice of Shareholders Meetings***

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public offer for our shares.

We must announce general meetings at least thirty-five days in advance by means of a preliminary notice (*avis de réunion*), which is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must first be sent to the French Financial markets authority (*Autorité des marchés financiers*, the *AMF*), with an indication of the date on which it will be published in the *BALO*. It must be published on our website at least twenty-one days prior to the general meeting. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders for consideration at the

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general meeting and a detailed description of the voting procedures (proxy voting, electronic voting or voting by mail), the procedures permitting shareholders to submit additional resolutions or items to the agenda and to ask written questions to the Board of Directors. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date, time and place of the meeting in a newspaper of national circulation in France and on our website.

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*.

### *Other issues*

In general, shareholders can only take action at shareholders' meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the appointment and dismissal of directors even if this action has not been included on the agenda.

Additional resolutions to be submitted for approval by the shareholders at the shareholders' meeting may be proposed to the Board of Directors, for recommendation to the shareholders at any time from the publication of the preliminary notice in the *BALO* until twenty-five days prior to the general meeting and in any case no later than twenty days following the publication of the preliminary notice in the *BALO* by:

one or several shareholders together holding a specified percentage of shares;

a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or

the works council.

Within the same period, the shareholders may also propose additional items (*points*) to be submitted and discussed during the shareholders' meeting, without a shareholders' vote. The shareholders must substantiate the reasons for proposing their proposals of additional items.

The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

The Board of Directors must submit the resolutions to a vote of the shareholders after having made a recommendation thereon. The Board of Directors may also comment on the items that are submitted to the shareholders' meeting.

Following the date on which documents must be made available to the shareholders (including documents to be submitted to the shareholders meeting and resolutions proposed by the Board of Directors, which must be published on our website at least twenty-one days prior to the general meeting), shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting or may refer to a Q&A section located on our website in which the question submitted by a shareholder has already been answered.

**Attendance at Shareholders Meetings; Proxies and Votes by Mail**

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.



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The right of shareholders to participate in general meetings is subject to the recording (*enregistrement comptable*) of their shares on the third business day, zero hour (Paris time), preceding the general meeting:

for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and

for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate (*attestation de participation*) enabling them to participate in the general meeting.

### ***Attendance in Person***

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code and our *statuts*.

### ***Proxies and Votes by Mail***

Proxies are sent to any shareholder upon a request received between the publication of the final notice of meeting and six days before the general meeting and must be made available on our website at least twenty-one days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice of the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to the meeting). A shareholder may grant proxies to any natural person or legal entity. The agent may be required to disclose certain information to the shareholder or to the public.

Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send to shareholders a voting form upon request or must make available a voting form on our website at least twenty-one days before the general meeting. The completed form must be returned to us at least three days prior to the date of the shareholders' meeting. For holders of registered shares, in addition to traditional voting by mail, instructions may also be given via internet.

### **Quorum**

The French Commercial Code requires that shareholders holding in the aggregate at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

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an ordinary general meeting; and

an extraordinary general meeting where the only resolutions pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public offer for our shares (article L. 233-32 of the French Commercial Code).

For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, held by shareholders present in person, voting by mail or by proxy.

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

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When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this *Quorum* section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

## **Votes Required for Shareholder Action**

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public offer for our shares (article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders' meeting and at any special meeting of holders of a specific category of shares, the affirmative vote of two-thirds of the votes cast is required.

Abstention from voting by those present or those represented by proxy or voting by mail is counted as a vote against the resolution submitted to a shareholder vote.

## **Changes to Shareholders' Rights**

Under French law, the affirmative vote of two-thirds of the votes cast at an extraordinary shareholders' meeting is required to change our *statuts*, which set out the rights attached to our shares, except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public offer for our shares (article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general shareholders' meeting. The quorum requirements for a special meeting are one-third of the voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholders' vote is required to increase the liabilities of shareholders.

## **Financial Statements and Other Communications with Shareholders**

In connection with any shareholders' meeting, we must provide a set of documents including our annual report and a summary of the financial results of the five previous fiscal years to any shareholder who so requests.

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We must also provide on our website at least twenty-one days before a shareholders' meeting certain information and a set of documents that includes the preliminary notice, the proxies and voting forms, the resolutions proposed by the Board of Directors, and the documents to be submitted to the shareholders' meeting pursuant to articles L.225-15 and R.225-83 of the French Commercial Code, etc. The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

### **Dividends**

We may only distribute dividends out of our distributable profits, plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our *statuts*. Distributable profits consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our *statuts*.

### ***Legal Reserve***

The French Commercial Code requires us to allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the

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amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2011, our legal reserve amounted to 282,280,863, representing 10.53% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may serve to allocate losses that may not be allocated to other reserves or may be distributed to shareholders upon liquidation of the company.

### ***Approval of Dividends***

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders meeting. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

### ***Distribution of Dividends***

Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board of Directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our *statuts* provide that, subject to a decision of the shareholders meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

### ***Timing of Payment***

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

## **Changes in Share Capital**

### ***Increases in Share Capital***

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As provided for by the French Commercial Code, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates (*directeurs généraux délégués*).

Increases in our share capital may be effected by:

issuing additional shares;

increasing the par value of existing shares;

creating a new class of equity securities; or

exercising the rights attached to securities giving access to the share capital.

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Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

in consideration for cash;

in consideration for assets contributed in kind;

through an exchange offer;

by conversion of previously issued debt instruments;

by capitalization of profits, reserves or share premium; or

subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public offer for our shares (article L. 233-32 of the French Commercial Code) require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings. See [Quorum](#) and [Votes Required for Shareholder Action](#) above.

On May 6, 2011, our shareholders approved various resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at 1.3 billion. This cap applies to all the resolutions whereby the extraordinary shareholders' meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

the maximum aggregate par value of capital increases that may be carried out with preemptive rights maintained was set at 1.3 billion;

the maximum aggregate par value of capital increases that may be carried out by public offering without preemptive rights was set at 520 million;

the maximum aggregate par value of capital increases that may be carried out by capitalization of share premium, reserves, profits or other items was set at 500 million; and

capital increases resulting in the issuance of securities to members of employee savings plans are limited to 1% of the share capital as computed on the date of the Board of Directors' decision to issue such securities, and such issuances may be made at a discount of 20% (or 30% if certain French law restrictions on resales were to apply).

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On May 6, 2011, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization, for a period of 26 months, to grant options to purchase or to subscribe for our shares to employees and/or corporate officers; such options may not give entitlement to a total number of shares exceeding 1% of the share capital as computed on the date of the decision of the Board of Directors to grant such options; see [Stock Options](#) above;

On April 17, 2009, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization, for a period of 38 months, to grant existing or new restricted shares to employees and/or corporate officers, up to a limit of 1% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see [Awards of Shares](#) above.

See also [Item 6. Directors, Senior Management and Employees](#) [E. Share Ownership](#) .



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### ***Decreases in Share Capital***

In accordance with the provisions of the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders' meeting may authorize the cancellation of up to a maximum of 10% of a company's share capital within any 24-month period. On May 6, 2011, our shareholders delegated to our Board of Directors for 26 months the right to reduce our share capital by canceling our own shares.

### **Preemptive Rights**

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a *pro rata* basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris Stock Exchange.

Preemptive rights with respect to any particular offering may be waived by the affirmative vote of shareholders holding two-thirds of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the issue of securities must be completed within the period prescribed by law. Shareholders may also notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the weighted average market prices of the shares for the last three trading days on Euronext Paris Stock Exchange prior to the determination of the subscription price of the capital increase less 5%.

### **Form, Holding and Transfer of Shares**

#### ***Form of Shares***

Our *statuts* provide that the shares may be held in either bearer form or registered form at the option of the holder.

***Holding of Shares***

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d'inscription en compte*) to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are

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credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and provides the account holder with a securities account statement. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal entity (*personne morale*) which holds more than 2.5% of our shares or voting rights, to disclose the name of any person who owns, directly or indirectly, more than one-third of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

### ***Transfer of Shares***

Our *statuts* do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the Euronext Paris Stock Exchange on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary.

A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. Registration duty is currently payable in France if a written deed of sale and purchase (*acte*) is executed in France or outside France with respect to the shares of the Company.

### **Redemption of Shares**

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders' meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following the acquisition. See also [Trading in Our Own Shares](#) below.

### **Sinking Fund Provisions**

Our *statuts* do not provide for any sinking fund provisions.

**Liability to Further Capital Calls**

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

**Liquidation Rights**

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the par value of their shareholdings.

**Requirements for Holdings Exceeding Certain Percentages**

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, 33 1/3%, 50%, 66 2/3%, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those

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percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

The AMF also requires disclosure of certain information relating to other financial instruments (e.g., convertible or exchangeable securities, warrants, equity swaps, etc.) that could increase the shareholding of the individual or entity.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20% or 25% of the outstanding shares or voting rights of a listed company in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross any such threshold.

In the report, the acquirer will have to specify its intentions for the following six months including:

- whether it acts alone or in concert with others;
- the means of financing of the acquisition (the notifier shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifier. The notifier shall also indicate what portion of its holding, if any, it obtained through securities loans);
- whether or not it intends to continue its purchases;
- whether or not it intends to acquire control of the company in question;
- the strategy it contemplates *vis-à-vis* the issuer;
- the way it intends to implement its strategy, including: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify the memorandum and articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;
- any agreement for the temporary transfer of shares or voting rights; and
- whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

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In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company.

In addition, our *statuts* provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights must notify us by

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certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our *statuts* apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement, will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

## **Change in Control/Anti-takeover**

There are no provisions in our *statuts* that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our *statuts* that allow the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other anti-takeover measures without a shareholder vote.

Our *statuts* do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

## **Trading in Our Own Shares**

Under French law, Sanofi may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. Prior to acquiring our shares, we must publish a description of the share repurchase program (*descriptif du programme de rachat d'actions*).

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed issued under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a *pro rata* basis.

On May 6, 2011, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each Sanofi ordinary share may not be greater than 80.00 and the maximum amount that Sanofi may pay for the repurchases is 10,487,982,240. This authorization was granted for a period of 18 months from May 6, 2011 and cancelled and replaced the authorization granted to the Board of Directors by the general meeting held on May 17, 2010. A description of this share repurchase

program as adopted by the Board of Directors on May 6, 2011, (*descriptif du programme de rachat d'actions*) was published on February 28, 2011.

***Purposes of Share Repurchase Programs***

European regulation 2273/2003, dated December 22, 2003 (which we refer to in this section as the Regulation ), in application of European directive 2003/6/EC, dated January 28, 2003, known as the Market Abuse Directive (the Directive ) relating to share repurchase programs and the stabilization of financial instruments, came into effect on October 13, 2004.

The entry into force of the Regulation has resulted in changes in the manner in which share repurchase programs are implemented. Under the Regulation, an issuer will benefit from a safe harbor for share transactions



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that comply with certain conditions relating in particular to the pricing, volume and timing of transactions (see below) and that are made in connection with a share repurchase program the purpose of which is:

to reduce the share capital through the cancellation of treasury shares; and/or

to meet obligations arising from debt instruments exchangeable into equity instruments and/or the implementation of employee share option programs or other employee share allocation plans.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor. However, as permitted by the Directive, which provides for the continuation of existing practices that do not constitute market manipulation and that conform with certain criteria set forth in European directive 2004/72, dated April 29, 2004, the AMF published exceptions on March 22, 2005, October 1, 2008 and March 21, 2011 to permit the following existing market practices:

transactions pursuant to a liquidity agreement entered into with a financial services intermediary that complies with the ethical code (*charte de déontologie*) approved by the AMF; and

the purchase of shares that are subsequently used as acquisition currency in a business combination transaction.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer's shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

### ***Pricing, Volume and Other Restrictions***

In order to qualify for the safe harbor, the issuer must generally comply with the following pricing and volume restrictions:

a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out;

subject to certain exceptions for illiquid securities, the issuer must not purchase more than 25% of the average daily volume of the shares in any one day on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, an issuer must not:

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sell treasury shares during the period of the repurchase program (without prejudice to the right of the issuer to meet its obligations under employee share option programs or other employee share allocation plans or to use shares as acquisition currency as mentioned above); it being further specified that such prohibition is not applicable in the event of off-market block trades or if the share repurchase program is implemented by a financial services intermediary pursuant to a liquidity agreement as mentioned above; and

effect any transaction during a blackout period imposed by the applicable law of the Member State in which the transaction occurs (*i.e.*, under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public and during the 30-day period preceding the date of publication of annual and half-year financial statements and the 15-day period preceding the date of publication of quarterly financial information), without prejudice to transactions carried out pursuant to a liquidity agreement as mentioned above; or

effect any transaction in securities with respect to which the issuer has decided to defer disclosure of any material, non-public information.

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### *Use of Share Repurchase Programs*

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2011, we used the authority delegated by our shareholders to repurchase our shares on the stock market.

Pursuant to our share repurchase program authorized by our shareholders in May 2011, we repurchased 21,655,140 of our shares for a weighted average price of 49.60.

On July 27, 2011, the Board of Directors cancelled 2,328,936 treasury shares, as follows:

2,125,000 shares repurchased in June 2011 pursuant to the share repurchase program of the Company;

203,936 shares previously allocated to expired stock option programs, which had been reallocated to the purpose of reducing the share capital.

On November 2, 2011, the Board of Directors cancelled 8,070,453 treasury shares repurchased in August and September 2011 pursuant to the share repurchase program of the Company;

In 2010, we also implemented the share repurchase program authorized by our shareholders in May 2010 with the aim of supporting the liquidity of the shares through a liquidity contract entered into with an investment service provider in compliance with the ethical code (*charte de déontologie*) approved by the AMF. We entered into this liquidity contract with Exane BNP Paribas on September 16, 2010. Upon implementation of this contract, we allocated 40,000,000, of which 20,000,000 was initially made available, to the liquidity account.

During 2011, pursuant to the liquidity contract, Exane BNP Paribas purchased 7,569,417 of our shares at an average weighted price of 50.69 and sold 7,584,417 of our shares at an average weighted price of 50.79.

In 2011, of the 5,851,776 shares allocated to stock purchase option plans outstanding at December 31, 2010, 85,660 shares were transferred to grantees of options,

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As a result, as of December 31, 2011, treasury shares were allocated as follows:

5,766,116 shares, representing 0.28% of our share capital, were allocated to outstanding stock purchase option plans;

11,459,687 directly-owned shares, representing 0.85% of our share capital, were allocated to cancellation; and

None of the shares was allocated to the liquidity account, even if the liquidity contract was outstanding.

As of December 31, 2011, we directly owned 17,225,803 Sanofi shares with a par value of 2 representing around 1.28% of our share capital and with an estimated value of 940,411,219, based on the share price at the time of purchase.

### ***Reporting Obligations***

Pursuant to the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

issuers must report all transactions in their own shares on their web site within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code approved by the AMF; and

issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis.

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### **Ownership of Shares by Non-French Persons**

The French Commercial Code and our *statuts* currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, non-residents of France must file an administrative notice with the French authorities in connection with the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of 33 <sup>1</sup>/<sub>3</sub>% or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

the acquiring party's intentions;

the acquiring party's ability to elect directors; or

financial reliance by the company on the acquiring party.

### **Enforceability of Civil Liabilities**

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our officers and directors reside outside the United States. In addition, a substantial portion of our assets is located in France.

As a result, it may be difficult for investors to effect service of process within the United States upon or obtain jurisdiction over our Company or our officers and directors in U.S. courts in actions predicated on the civil liability provisions of the U.S. securities law. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under the U.S. federal securities laws. There is doubt as to the enforceability against such persons in France, whether in original actions or in actions to enforce judgments of U.S. courts, of liabilities based solely on the U.S. federal securities laws. Actions for enforcement of foreign judgments against such persons would require such persons who are of French nationality to waive their right under Article 15 of the French Civil Code to be sued only in France. We believe that no such French persons have waived such right with respect to actions predicated solely upon U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law No. 80-538 of July 16, 1980, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with such actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.

### ***C. Material Contracts***

#### *The Facilities Agreement*

In connection with the launch of its public tender offer for Genzyme, Sanofi executed on October 2, 2010 a Term Facilities Agreement (the Facilities Agreement ) with J.P. Morgan plc, Société Générale Corporate & Investment Banking and BNP Paribas (the Initial Mandated Lead

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Arrangers ) which was further syndicated by the Initial Mandated Lead Arrangers among other financial institutions, for two unsecured term loan facilities available for drawn downs of up to U.S.\$15,000,000,000 in the aggregate for the purpose of financing part of the acquisition of Genzyme Corporation composed of:

A U.S.\$10,000,000,000 term facility ( Facility A ) maturing 18 months from October 2, 2010, the date of execution of the Facilities Agreement, with an optional six-month extension.

A U.S.\$5,000,000,000 term facility ( Facility B ) with final maturity at 42 months from the date of execution of the Facilities Agreement.

The interest rate on each facility was equal to the London Inter-Bank Overnight Rate (or Libor), plus an applicable margin.

On March 29, 2011, available commitments under Facility A were reduced by an amount equivalent to the proceeds of an SEC-registered U.S. bond issue (approximately \$7 billion). The remaining unused commitments of this facility were cancelled on April 1, 2011. On April 5, 2011, Sanofi drew down \$4 billion under Facility B, and cancelled the remaining balance of \$1 billion. On June 28, August 5 and November 3, 2011 Sanofi made early repayments of respectively \$1 billion, \$1 billion, \$2 billion of the Facility B drawdown.

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As a result, the Facility B drawdown was fully repaid as of November 3, 2011 and as a consequence, the entire Facilities Agreement expired.

A copy of the Facilities Agreement and an amendment dated February 15, 2011 are on file with the SEC as exhibits 4.1 and 4.2 hereto. Reference is made to such exhibits for a more complete description of the terms and conditions of the Acquisition Facility as amended, and the foregoing summary of such terms and conditions is qualified in its entirety by such exhibits.

### *The Agreement and Plan of Merger*

On February 16, 2011, Sanofi and its wholly owned subsidiary GC Merger Corp. signed an Agreement and Plan of Merger governed by the laws of the Commonwealth of Massachusetts, and subject to the jurisdiction of the courts of the Commonwealth of Massachusetts (the Merger Agreement), with Genzyme Corporation (Genzyme). Pursuant to the Merger Agreement, among other things, Sanofi and GC Merger Corp. agreed to amend the outstanding tender offer to acquire all of the outstanding shares of common stock of Genzyme (the Genzyme Shares) in order to increase the price per share from \$69 to \$74 in cash (the Cash Consideration) plus one contingent value right (a CVR) to be issued by Sanofi subject to and in accordance with a CVR Agreement described below (collectively, the Merger Consideration) per Genzyme Share. The Merger Agreement also provided that, subject to the satisfaction or waiver of certain conditions, following consummation of the Amended Offer, GC Merger Corp. would be merged with and into Genzyme, with Genzyme surviving the Merger as a wholly-owned subsidiary of Sanofi (the Merger).

The transaction was completed on April 8, 2011 in accordance with the terms of the Merger Agreement and the public exchange offer at a price of \$74 in cash plus the issuance to Genzyme shareholders of one contingent value right (CVR) per Genzyme share. The CVRs are listed on the NASDAQ market and Genzyme is now a fully-consolidated subsidiary.

### *The Contingent Value Rights Agreement.*

On March 30, 2011, Sanofi and the American Stock Transfer & Trust Company, LLC, as trustee entered into a Contingent Value Rights agreement governed by the laws of the State of New York and subject to the jurisdiction of the courts of the State of New York (CVR Agreement) governing the terms of the CVRs.

Pursuant to the terms of the CVR Agreement, a holder of a CVR is entitled to cash payments upon the achievement of certain milestones, including based on production levels of Cerezyme<sup>®</sup> and Fabrazyme<sup>®</sup>, U.S. regulatory approval of alemtuzumab for treatment of multiple sclerosis (Lemtrada), and on achievement of certain aggregate Lemtrada sales thresholds, as follows:

*Cerezyme<sup>®</sup>/Fabrazyme<sup>®</sup> Production Milestone Payment.* \$1 per CVR, if both Cerezyme<sup>®</sup> production met or exceeded 734,600 400-unit vial equivalents and Fabrazyme<sup>®</sup> production met or exceeded 79,000 35mg vial equivalents during calendar year 2011. This milestone was not met and hence was not paid.

*Approval Milestone Payment.* \$1 per CVR upon receipt by Genzyme or any of its affiliates, on or before March 31, 2014, of the approval by the U.S. Food and Drug Administration of Lemtrada for treatment of multiple sclerosis.

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*Product Sales Milestone #1 Payment.* \$2 per CVR if Lemtrada net sales post launch exceeds an aggregate of \$400 million within specified periods and territories.

*Product Sales Milestone #2 Payment.* \$3 per CVR upon the first instance in which global Lemtrada net sales for a four calendar quarter period are equal to or in excess of \$1.8 billion. If Product Sales Milestone #2 is achieved but the Approval Milestone was not achieved prior to March 31, 2014, the milestone payment amount will be \$4 per CVR (however, in such event the Approval Milestone shall not also be payable).

*Product Sales Milestone #3 Payment.* \$4 per CVR upon the first instance in which global Lemtrada net sales for a four calendar quarter period are equal to or in excess of \$2.3 billion (no quarter in which global Lemtrada net sales were used to determine the achievement of Product Sales Milestone #1 or #2 shall be included in the calculation of sales for determining whether Product Sales Milestone #3 has been achieved).



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*Product Sales Milestone #4 Payment.* \$3 per CVR upon the first instance in which global Lemtrada net sales for a four calendar quarter period are equal to or in excess of \$2.8 billion (no quarter in which global Lemtrada net sales were used to determine the achievement of Product Sales Milestone #1, #2 or #3 shall be included in the calculation of sales for determining whether Product Sales Milestone #4 has been achieved).

The CVRs will expire and no payments will be due under the CVR agreement on the earlier of (a) December 31, 2020 and (b) the date that Product Sales Milestone #4 is paid.

Sanofi has agreed to use commercially reasonable efforts to achieve the Cerezyme®/Fabrazyme® Production Milestone, and diligent efforts (as defined in the CVR Agreement) to achieve each of the other milestones above. Sanofi has also agreed to use its commercially reasonable efforts to maintain a listing for trading of the CVRs on Nasdaq.

The CVR Agreement does not prohibit Sanofi or any of its subsidiaries or affiliates from acquiring the CVRs, whether in open market transactions, private transactions or otherwise; Sanofi has certain disclosure obligations in connection with such acquisitions under the CVR Agreement. On or after the third anniversary of the launch of Lemtrada, Sanofi may also, subject to certain terms and conditions as set forth in the CVR Agreement, optionally purchase and cancel all (but not less than all) of the outstanding CVRs at the average trading price of the CVRs if the volume-weighted average CVR trading price is less than fifty cents over forty-five trading days and Lemtrada sales in the prior four quarter period were less than one billion U.S. dollars in the aggregate.

A copy of the Merger Agreement and the form of CVR Agreement are on file with the SEC as exhibits 4.3 and 4.4 hereto, respectively. Reference is made to such exhibits for a more complete description of the terms and conditions of the Merger Agreement and the CVR Agreement, and the foregoing summary of such terms and conditions is qualified in its entirety by such exhibits.

### ***D. Exchange Controls***

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary. In France, all registered banks and most credit establishments are accredited intermediaries.

### ***E. Taxation***

#### **General**

The following generally summarizes the material French and U.S. federal income tax consequences to U.S. holders (as defined below) of owning and disposing of our ADSs and ordinary shares (collectively the Securities). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

*This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any U.S. federal, state, local or other national tax laws.*

The description of the French and U.S. federal income tax consequences set forth below is based on the laws (including, for U.S. federal income tax purposes, the Internal Revenue Code of 1986, as amended (the Code ), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the Treaty ), which entered into force on December 30, 1995 (as amended by any subsequent protocols, including

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the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities (the Regulations ) in force as of the date of this report. *U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the Limitations on Benefits provision, in light of their own particular circumstances.*

For the purposes of this discussion, a U.S. holder is a beneficial owner of Securities that is (i) an individual who is a U.S. citizen or resident for U.S. federal income tax purposes, (ii) a U.S. domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) otherwise subject to U.S. federal income taxation on a net income basis in respect of Securities. A non-U.S. holder is a person other than a U.S. holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a U.S. holder is a partner in a partnership that holds Securities, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

French law has enacted new rules relating to trusts, in particular a specific new tax and filing requirements as well as modifications to wealth, estate and gift taxes as they apply to trusts. Given the complex nature of these new rules and the fact that their application varies depending on the status of the trust, the grantor, the beneficiary and the assets held in the trust, the following summary does not address the tax treatment of Securities held in a trust. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets that have the U.S. dollar as their functional currency, that are entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for U.S. federal income tax purposes and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and U.S. federal income tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

## **French Taxes**

### *Estate and Gift Taxes and Transfer Taxes*

In general, a transfer of Securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment

or a fixed base in France.

Generally, transfers of Securities (other than ordinary shares) are not subject to French registration or stamp duty. Transfers of ordinary shares issued by a listed French company such as Sanofi will not be subject to French registration or stamp duty if such transfers are not evidenced by a written agreement (*acte*). However, if the transfer is evidenced by a written agreement executed either in France or outside France, the transfer of ordinary

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shares would be subject to transfer duty at (i) 3% for the portion of the sale price below 200,000, (ii) 0.5% for the portion of the sale price between 200,000 and 500,000,000, and (iii) 0.25% for the portion of the sale price exceeding 500,000,000.

### *Wealth Tax*

The French wealth tax *impôt de solidarité sur la fortune* applies only to individuals and does not generally apply to the Securities if the holder is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 25% of the financial rights.

### **U.S. Taxes**

#### *Ownership of the Securities*

Deposits and withdrawals by a U.S. holder of ordinary shares in exchange for ADSs, will not be taxable events for U.S. federal income tax purposes. For U.S. tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs. Accordingly, the discussion that follows regarding the U.S. federal income tax consequences of acquiring, owning and disposing of ordinary shares is equally applicable to ADSs.

#### *Information Reporting and Backup Withholding Tax*

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

#### *State and Local Taxes*

In addition to U.S. federal income tax, U.S. holders of Securities may be subject to U.S. state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of U.S. state and local income tax law to their particular situation.*

**ADSs-Ordinary Shares**

**French Taxes**

*Taxation of Dividends*

Under French law, dividends paid by a French corporation, such as Sanofi, to non-residents of France are generally subject to French withholding tax at a rate of 30% (21% for distributions made to individuals that are resident in the European Economic Area, and 15% for distributions made to non-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206-5 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the administrative guidelines 4 H-2-10 of January 15, 2010). Dividends paid by a French corporation, such as Sanofi, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French withholding tax at a rate of 55%, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such States or territories; however, eligible U.S. holders entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, and receiving dividends in non-cooperative States or territories will not be subject to this 55% withholding tax rate.

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Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident, as defined pursuant to the provisions of the Treaty, whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France is reduced to 15% or 5% if such U.S. holder owns directly or indirectly at least 10% of the share capital of the issuing company and such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates, contained in the Limitation on Benefits provision of the Treaty are complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. holder, may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depository with a treaty form (Form 5000). Dividends paid to a U.S. holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 30% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Form 5000 and Form 5001, together with instructions, will be provided by the depository to all U.S. holders registered with the depository and is also available from the U.S. Internal Revenue Service. The depository will arrange for the filing with the French Tax authorities of all such forms properly completed and executed by U.S. holders of ordinary shares or ADSs and returned to the depository in sufficient time that they may be filed with the French tax authorities before the distribution so as to obtain immediately a reduced withholding tax rate.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

### *Tax on Sale or Other Disposition*

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. Special rules apply to holders who are residents of more than one country.

## **U.S. Taxes**

### *Taxation of Dividends*

For U.S. federal income tax purposes, the gross amount of any distribution paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under U.S. federal income tax principles). Dividends paid by Sanofi will not be eligible for the

dividends-received deduction generally allowed to corporate U.S. holders.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual U.S. holder with respect to taxable years beginning before January 1, 2013, with respect to the ADSs or our ordinary shares will be subject to taxation at a maximum rate of 15% if the dividends are qualified dividends. Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a



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passive foreign investment company ( PFIC ). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for U.S. federal income tax purposes with respect to its 2011 taxable year. In addition, based on its audited financial statements and current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that Sanofi will become a PFIC for its 2012 taxable year.  *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a U.S. holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as passive category income (or, in the case of certain U.S. holders, general category income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a U.S. holder's expected economic profit is insubstantial.  *The U.S. federal income tax rules governing the availability and computation of foreign tax credits are complex. U.S. holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a U.S. holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder's tax basis in its ordinary shares or ADSs and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see Tax on Sale or Other Disposition, below).

The amount of any distribution paid in euros will be equal to the U.S. dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of ordinary shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into U.S. dollars on such date.  *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a U.S. holder or depositary that are converted into U.S. dollars on a date subsequent to receipt.*

Distributions to holders of additional ordinary shares (or ADSs) with respect to their ordinary shares (or ADSs) that are made as part of a pro rata distribution to all ordinary shareholders generally will not be subject to U.S. federal income tax. However, if a U.S. holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder's tax basis in the distributed shares (or ADSs) will be equal to such amount.

### *Tax on Sale or Other Disposition*

In general, for U.S. federal income tax purposes, a U.S. holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the ordinary shares or ADSs and the U.S. holder's adjusted tax basis (determined in U.S. dollars and under U.S. federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be U.S.-source gain or loss, and will be treated as long-term capital gain or loss if the U.S. holder's holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the U.S. holder is an individual, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 15%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.



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***F. Dividends and Paying Agents***

N/A

***G. Statement by Experts***

N/A

***H. Documents on Display***

We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, and, in accordance therewith, we are required to file reports, including annual report on Form 20-F, and other information with the U.S. Securities and Exchange Commission by electronic means. Our public filings are available to the public over the Internet at the Commission's Website at <http://www.sec.gov> (these documents are not incorporated by reference in this annual report).

***I. Subsidiary Information***

N/A

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### **Item 11. Quantitative and Qualitative Disclosures about Market Risk<sup>(1)</sup>**

#### **General Policy**

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risk, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage these risks centrally, in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions, credit facilities and/or currency lines, guaranteed whenever necessary by the parent company are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our investment and financing strategies, as well as our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy on derivatives prohibits speculative exposure.

#### **Liquidity Risk**

We operate a centralized treasury platform according to which all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages the Group's current and projected financing (debt, net of cash and cash equivalents), and ensures that the Group is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt.

The Group tends to diversify its short term investments with leading banks on money market products available on sight or which maturity is lower than three months. As of December 31, 2011, cash and cash equivalents amounted to 4,124 million and short term investments were mainly made of:

collective investments in short-term money market and money market euro-denominated Funds based on the European classification used by the *Autorité des Marchés Financiers*, and in money market U.S. dollar-denominated Funds subject to the U.S. Securities and Exchange Commission regulation 2a7. All such Funds can be traded on a daily basis and are used within a limit of 10% of held assets;

bank term deposits with a maturity lower than three months. These short-term investments are entered into with leading financial institutions; and

term deposits with a maturity lower than three months. These short-term investments are entered into with non financial institutions.

As of December 31, 2011, the Group had 10.0 billion of undrawn general corporate purpose confirmed credit facilities, of which 3 billion expire in 2012, 0.7 billion in 2015 and 6.3 billion in 2016. Our credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding through public or private issuances of debt securities, in the United States and in France (Euro Medium Term Note program), and by issuing commercial paper in the United States and in France. The average duration of the total debt was 3.5 years as of December 31, 2011, compared to 3.9 years as of December 31, 2010. Short-term commercial paper programs (U.S. dollar-denominated commercial paper swapped into euro and euro-denominated commercial paper) are used to meet our short-term financing needs. Drawdowns under these programs are generally renewed for periods of 2 months. In 2011, the average drawdowns under these programs was 3.4 billion (maximum 6.2 billion). As of December 31, 2011, the drawdown under these programs amounted to 0.7 billion.

In the context of a market-wide liquidity crisis and/or a downgrade of its rating, the Group could be exposed to difficulties to call up its cash available, a scarcity of its sources of funding including the above-mentioned programs, or to a deterioration of their conditions. This situation could damage the capacity of the Group to refinance its debt or to issue new debt at reasonable conditions.

**Table of Contents****Interest Rate Risk**

Having financed the Genzyme acquisition, the Group manages its net debt in two currencies – euro and U.S. dollar (see note D.17 to the consolidated financial statements). With the variable portion of the debt, the Group is exposed to interest rate increases, largely those of Eonia and Euribor for the euro debt and U.S. Libor and Federal Fund Effective for the U.S. dollar debt. In this context, in order to minimize cost of debt or volatility, the Group uses interest rate swaps, multi-currency interest rate swaps and interest rate options which change the fixed rate / variable rate breakdown of its debt. The derivative instruments are denominated either in euros or in U.S. dollars.

As of December 31, 2011, the sensitivity of the total debt, net of cash and cash equivalents to interest rate fluctuations over a full year is as follows:

	<b>Impact on</b>
	<b>pre-tax</b>
	<b>net income</b>
	<b>( million)</b>
<b>Change in 3-month Euribor</b>	
+ 100 bp	(33)
+ 25 bp	(9)
- 25 bp	10
- 100 bp	41

**Foreign Exchange Risk*****a. Operational Foreign Exchange Risk***

A substantial proportion of our net sales is generated in countries in which the euro, which is our reporting currency, is not the functional currency. In 2011, for example, 29.8% of our consolidated net sales were generated in the United States. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on net sales. Consequently, our operating income may be materially affected by fluctuations in the exchange rate between the euro and other currencies, primarily the U.S. dollar.

We operate a foreign exchange risk hedging policy to reduce the exposure of our operating income to exchange rate movements. This policy involves regular assessments of our worldwide foreign currency exposure, based on budget estimates of foreign-currency transactions to be carried out by the parent company and its subsidiaries. These transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of these transactions to exchange rate movements, we may contract currency hedges using liquid financial instruments such as forward purchases and sales of currency as well as call and put options, and combinations of currency options (collars).

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The table below shows operational currency hedging derivatives in place as of December 31, 2011, with the notional amount translated into euros at the relevant closing exchange rate. See also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2011.

**Operational foreign exchange derivatives as of December 31, 2011 <sup>(1)</sup>:**

<i>( million)</i>	<b>Notional amount</b>	<b>Fair value</b>
<b>Forward currency sales</b>	<b>3,446</b>	<b>(96)</b>
<i>Of which U.S. dollar</i>	1,779	(59)
<i>Japanese yen</i>	685	(22)
<i>Russian ruble</i>	310	(5)
<i>Singaporean dollar</i>	71	
<i>Australian dollar</i>	63	(2)
<b>Forward currency purchases</b>	<b>1,077</b>	<b>7</b>
<i>Of which Singaporean dollar</i>	357	4
<i>Swiss franc</i>	165	2
<i>Japanese yen</i>	124	3
<i>Hungarian forint</i>	107	(4)
<i>U.S. dollar</i>	69	
<b>Total</b>	<b>4,523</b>	<b>(89)</b>

*(1) As of December 31, 2010, the notional amount of forward currency sales was 2,444 million with a fair value of - 25 million (including forward sales of U.S. dollars of a notional amount of 1,380 million with a fair value of - 12 million). As of December 31, 2010, the notional amount of forward currency purchases was 257 million with a fair value of - 2 million (including forward sales of U.S. dollars of a notional amount of 51 million with a fair value of - 1 million).*

As of December 31, 2011, none of these instruments had an expiry date after December 31, 2012 except for a specific forward currency purchase position for a total amount of £40 million whose maturity goes until 2015.

These positions mainly hedge future foreign-currency cash flows arising after the balance sheet date in relation to transactions carried out during the year ended December 31, 2011 and recognized in the balance sheet at that date. Gains and losses on derivative instruments (forward contracts) have been and will continue to be calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship the foreign exchange profit and loss on these items (derivative instruments and underlying assets as of December 31, 2011) will be close to zero in 2012.

**b. Financial Foreign Exchange Risk**

Some of our financing activities, such as the cash pooling arrangements for foreign subsidiaries outside the euro zone and our U.S. commercial paper issues, expose certain entities to financial foreign exchange risk (i.e., the risk of changes in the value of loans and borrowings denominated in a currency other than the functional currency of the lender or borrower). The net foreign exchange exposure mainly concerns the holding company and is hedged by firm financial instruments, usually forward contracts and currency swaps.

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The table below shows financial currency hedging instruments in place as of December 31, 2011, calculated using exchange rates prevailing as of that date. See also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2011.

**Financial foreign exchange derivatives as of December 31, 2011 <sup>(1)</sup>:**

( million)	Notional amount	Fair value	Expiry
<b>Forward currency purchases</b>	<b>2,719</b>	<b>24</b>	
Of which Pound sterling	843	5	2012
U.S. dollar	828	10	2012
Swiss franc	274	1	2012
<b>Forward currency sales</b>	<b>4,900</b>	<b>(104)</b>	
Of which U.S. dollar	2,964	(89)	2012
Japanese yen	993	(17)	2012
Czech koruna	251	4	2012
<b>Total</b>	<b>7,619</b>	<b>(80)</b>	

<sup>(1)</sup> As of December 31, 2010, the notional amount of forward currency purchases was 2,086 million with a fair value of - 13 million (including forward purchases of U.S. dollars of a notional amount of 814 million with a fair value of - 8 million). As of December 31, 2010, the notional amount of forward currency sales was 2,728 million with a fair value of - 64 million (including forward sales of U.S. dollars of a notional amount of 862 million with a fair value of - 26 million).

These forward contracts generate a net financial foreign exchange gain or loss arising from the interest rate gap between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency liabilities and receivables is offset by the change in the intrinsic value of the hedging instruments.

As of December 31, 2011, none of the instruments had an expiry date after September 30, 2012.

We may also hedge some future foreign-currency investment or divestment cash flows.

**c. Other Foreign Exchange Risks**

A significant proportion of our consolidated net assets is denominated in U.S. dollars. For a breakdown of net assets see Note D.35.2 to the consolidated financial statement. As a result, any fluctuation in the exchange rate of the U.S. dollar against the euro affects our equity, which can lead us to contract hedges of our net investments in foreign operations. As of December 31, 2011, we had no derivative instruments in place to limit the effect of such fluctuations.

The Group operates a substantial portion of its activity within the euro zone and holds a significant part of its indebtedness and cash and cash equivalent in euro. Euro is also the reporting currency of the Group. In the specific context of the sovereign debt crisis affecting certain European countries, the alleged or actual disruption in the use of the euro as currency in one or more European Monetary Union countries and



the associated fluctuations in currency exchange rates could have a material effect on our financial condition and earnings, the magnitude and consequences of which are unpredictable.

**Counterparty Risk**

Our financing and investing operations as well as our currency and interest rate hedges, are contracted with leading banks. We set limits for investment and derivative transactions with individual banks, depending on the rating of each bank. Compliance with these limits, which are based on notional amounts weighted by the residual maturity and the nature of the commitment is monitored on a daily basis.

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The table below shows our total exposure as of December 31, 2011 by rating and in terms of our percentage exposure to the dominant counterpart:

( million)	Cash and cash equivalent (mutual funds excluded) <sup>(1)</sup>	Notional amounts of currency hedges <sup>(2)</sup>	Notional amounts of interest hedges	General corporate purpose credit facilities
AAA	200			
AA-	803	3,254	2,523	2,757
A+	552	6,422	2,433	4,136
A	374	2,964	1,777	3,107
A-	60			
BBB ratings and not rated	99			
Not splitted	157			
<b>Total</b>	<b>2,245</b>	<b>12,640</b>	<b>6,733</b>	<b>10,000</b>
% / rating of the dominant counterparty	23% / AA-	17% / A+	10% / AA-	7% / A

<sup>(1)</sup> The cash equivalents include mutual funds investments for 1 879 million.

<sup>(2)</sup> The notional amounts are computed on the basis of the forward rates negotiated at the inception date of the derivative instruments.

Mutual funds investments are made by the Sanofi parent company. These mutual funds investments, are short-term money market and money market euro-denominated Funds based on the European classification used by the *Autorité des Marchés Financiers*, and money market U.S. dollar-denominated Funds subject to the U.S. Securities and Exchange Commission regulation 2a7. They show low volatility, low sensitivity to interest rate risk and a very low probability of loss of principal. Depository banks of the mutual funds as well as depositories of sanofi-aventis are at least A+ rated.

Realization of counterparty risk could impact our liquidity in certain circumstances.

**Stock Market Risk**

It is our policy not to trade on the stock market for speculative purposes.

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### **Item 12. Description of Securities other than Equity Securities**

#### **12.A Debt Securities**

Not applicable.

#### **12.B Warrants and Rights**

Not applicable.

#### **12.C Other Securities**

Not applicable.

#### **12.D American Depositary Shares**

### **General**

JPMorgan Chase Bank, N.A. ( JPMorgan ), as depositary, issues Sanofi ADSs in certificated form (evidenced by an American depositary receipt, or ADR) or book-entry form. Each ADR is a certificate evidencing a specific number of Sanofi ADSs. Each Sanofi ADS represents one-half of one Sanofi ordinary share (or the right to receive one-half of one Sanofi ordinary share) deposited with the Paris, France office of BNP Paribas, as custodian. Each Sanofi ADS also represents an interest in any other securities, cash or other property that may be held by the depositary under the deposit agreement. The depositary's office is located at 1 Chase Manhattan Plaza, Floor 58, New York, New York 10005-1401.

A holder may hold Sanofi ADSs either directly or indirectly through his or her broker or other financial institution. The following description assumes holders hold their Sanofi ADSs directly, in certificated form evidenced by ADRs. Holders who hold the Sanofi ADSs indirectly must rely on the procedures of their broker or other financial institution to assert the rights of ADR holders described in this section. Holders should consult with their broker or financial institution to find out what those procedures are.

We do not treat holders of Sanofi ADSs as one of our shareholders, and such holders do not have shareholder rights. French law governs shareholder rights. The depositary is the holder of the Sanofi ordinary shares underlying holders' Sanofi ADSs. The rights of holders of Sanofi ADSs are set forth in the deposit agreement between Sanofi and JPMorgan and in the ADR. New York law governs the deposit agreement and the ADRs.

The following is a summary of certain terms of the deposit agreement, as amended. The form of our deposit agreement has been filed as an exhibit to our Form F-6 filed on August 7, 2007, and the amendment to our deposit agreement has been filed as an exhibit to Post-Effective Amendment No. 1 to our Form F-6 filed on April 30, 2011. Each of the form and the amendment is incorporated by reference into this document. For more complete information, holders should read the entire deposit agreement (including the amendment) and the ADR itself. Holders may also inspect a copy of the deposit agreement at the depositary's office.

## **Share Dividends and Other Distributions**

### *Receipt of dividends and other distributions*

The depositary has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees and expenses. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

*Cash.* The depositary will convert any cash dividend or other cash distribution paid on the shares into U.S. dollars if, in its judgment, it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If the depositary determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depositary may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

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In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into U.S. dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depositary cannot convert euros into U.S. dollars may result in holders losing some or all of the value of a distribution.***

***Shares.*** The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depositary may distribute fractional Sanofi ADSs. If the depositary does not distribute additional Sanofi ADSs, the outstanding ADRs will also represent the new shares. The depositary may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.

***Rights to Receive Additional Shares.*** If we offer holders of Sanofi ordinary shares any rights to subscribe for additional shares or any other rights, the depositary, after consultation with us, will, in its discretion, either (1) make these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder's behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

U.S. securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

***Other Distributions.*** The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the U.S. Securities Act of 1933, as amended. We also have no obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to such holders.

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*Elective Distributions.* Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

## **Deposit, Withdrawal and Cancellation**

### ***Delivery of ADRs***

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

### ***Obtaining Sanofi ordinary shares***

A holder may turn in his or her ADRs at the depositary's office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any other deposited securities underlying the ADR at the office of a custodian or, at the holder's request, risk and expense, the depositary will deliver the deposited securities at its office.

## **Voting Rights**

A holder may instruct the depositary to vote the Sanofi ordinary shares underlying his or her Sanofi ADSs at any meeting of Sanofi shareholders, but only if we ask the depositary to ask for holder instructions. Otherwise, holders will not be able to exercise their right to vote unless they withdraw the underlying ordinary shares from the ADR program and vote as an ordinary shareholder. However, holders may not know about the meeting sufficiently in advance to timely withdraw the underlying ordinary shares.

If we ask for holder instructions in connection with a meeting of Sanofi shareholders, the depositary will mail materials to holders of Sanofi ADSs in the manner described under the heading "Notices and Reports; Rights of Holders to Inspect Books" below. For any instructions to be valid, the depositary must receive them on or before the date specified in the materials distributed by the depositary. The depositary will try, as far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as holders may validly instruct. The depositary will only vote or attempt to vote shares as holders validly instruct.

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We cannot assure holders that they will receive the voting materials in time to ensure that holders can instruct the depository to vote their shares. As long as they act in good faith, neither the depository nor its agents will be responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. ***This means that holders may not be able to exercise their right to vote and there may be nothing holders can do if their shares are not voted as they requested.***

Similar to our shares, Sanofi ADSs evidenced by ADRs that are registered in the name of the same owner for at least two (2) years are eligible for double voting rights so long as certain procedures are followed, as set out in the deposit agreement. For additional information regarding double voting rights, see Item 10. Additional Information B. Memorandum and Articles of Association Voting Rights .

The deposit agreement allows the depository and Sanofi to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate to comply with French or United States law or our *statuts*. ***For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders meeting in order to be allowed to give voting instructions.***



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**Notices and Reports; Rights of Holders to Inspect Books**

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any cash or other distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given.

The depositary will make available for inspection by ADS holders at the depositary's office any reports and communications, including any proxy soliciting material, received from us that are both (1) received by the depositary as the holder of the deposited securities and (2) made generally available to the holders of such deposited securities by us. The depositary will also, upon written request, send to ADS holders copies of such reports when furnished by us pursuant to the deposit agreement. Any such reports and communications, including any such proxy soliciting material, furnished to the depositary by us will be furnished in English to the extent such materials are required to be translated into English pursuant to any regulations of the SEC.

The depositary will keep books for the registration of ADRs and transfers of ADRs that at all reasonable times will be open for inspection by the holders provided that such inspection is not for the purpose of communicating with holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

**Fees and Expenses**

**Fees Payable By ADS Holders**

Pursuant to the deposit agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

<b>Associated Fee</b>	<b>Depositary Action</b>
\$5.00 or less per 100 ADSs (or portion thereof)	Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the deposit agreement
\$0.02 or less per ADS (or portion thereof)	Any cash distribution made pursuant to the deposit agreement, including, among other things:

cash distributions or dividends,

distributions other than cash, shares or rights,

distributions in shares, and

rights of any other nature, including rights to subscribe for additional shares.

Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals

As applicable

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<b>Associated Fee</b>	<b>Depository Action</b>
A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	Distributions of securities other than cash, shares or rights
Any other charges payable by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)	Servicing of shares or other deposited securities
Expenses incurred by JPMorgan	Cable, telex and facsimile transmission (where expressly provided for in the deposit agreement)
	Foreign currency conversion into U.S. dollars

In addition to the fees outlined above, each holder will be responsible for any taxes or other governmental charges payable on his or her Sanofi ADSs or on the deposited securities underlying his or her Sanofi ADSs. The depository may refuse to transfer a holder's Sanofi ADSs or allow a holder to withdraw the deposited securities underlying his or her Sanofi ADSs until such taxes or other charges are paid. It may apply payments owed to a holder or sell deposited securities underlying a holder's Sanofi ADSs to pay any taxes owed, and the holder will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of Sanofi ADSs to reflect the sale and pay to the holder any proceeds, or send to the holder any property, remaining after it has paid the taxes.

***Fees Paid to Sanofi by the Depository***

JPMorgan, as depository, has agreed to reimburse Sanofi up to \$4,000,000 per year for expenses Sanofi incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants' fees in relation to our annual report on Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the shareholders. From January 1, 2011 to December 31, 2011, Sanofi received from JPMorgan reimbursements equal to the \$4,000,000 ceiling for expenses incurred in 2011. In addition to such reimbursements, JPMorgan has agreed to waive up to \$425,000 annually in servicing fees Sanofi may incur in connection with routine corporate actions such as annual general meetings and dividend distributions, as well as for other assistance JPMorgan may provide Sanofi, such as tax and regulatory compliance fees and investor relations advisory services.

**Changes Affecting Deposited Securities**

If we:

change the nominal or par value of our Sanofi ordinary shares;

recapitalize, reorganize, merge or consolidate, liquidate, sell assets, or take any similar action;

reclassify, split up or consolidate any of the deposited securities; or

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distribute securities on the deposited securities that are not distributed to holders;

then either:

the cash, shares or other securities received by the depositary will become deposited securities and each Sanofi ADS will automatically represent its equal share of the new deposited securities; or

the depositary may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

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### **Disclosure of Interests**

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to holders and any other persons, other than the depositary, who have an interest in the Sanofi ADSs. The consequences for failing to comply with these provisions are the same for holders and any other persons with an interest as a holder of our ordinary shares. For additional information regarding these obligations, see Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages .

### **Amendment and Termination**

We may agree with the depositary to amend the deposit agreement and the ADRs without the consent of the ADS holders for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of holders of Sanofi ADSs, it will only become effective 30 days after the depositary notifies such holders of the amendment. However, we may not be able to provide holders of Sanofi ADSs with prior notice of the effectiveness of any modifications or supplements that are required to accommodate compliance with applicable provisions of law, whether or not those modifications or supplements could be considered to be materially prejudicial to the substantial rights of holders of Sanofi ADSs. *At the time an amendment becomes effective, such holders will be considered, by continuing to hold their ADR, to have agreed to the amendment and to be bound by the ADR and the deposit agreement as amended.*

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify holders of Sanofi ADSs at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

### **Limitations on Obligations and Liability to Holders of Sanofi ADSs**

The deposit agreement expressly limits our obligations and the obligations of the depositary, and it limits our liability and the liability of the depositary. We and the depositary:

are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;

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are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;

are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;

have no obligation to become involved in a lawsuit or other proceeding related to the Sanofi ADSs or the deposit agreement on holders' behalf or on behalf of any other party, unless indemnity satisfactory to it against all expense and liability is furnished as often as may be required;

are not liable for the acts or omissions made by any securities depository, clearing agency or settlement system or the insolvency of the custodian to the extent the custodian is not a branch or affiliate of JPMorgan;

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may rely without any liability upon any written notice, request or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and

are not liable for any action or nonaction taken in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any ADS holder, or any other person believed in good faith to be competent to give such advice or information.

In addition, the depositary will not be liable for any acts or omissions made by a successor depositary. Moreover, neither we nor the depositary nor any of our respective agents will be liable to any holder of Sanofi ADSs for any indirect, special, punitive or consequential damages.

Pursuant to the terms of the deposit agreement, we and the depositary have agreed to indemnify each other under certain circumstances.

## **Requirements for Depositary Actions**

Before the depositary will deliver or register the transfer of Sanofi ADSs, make a distribution on Sanofi ADSs or process a withdrawal of shares, the depositary may require:

payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

## **Right to Receive the Shares Underlying the Sanofi ADSs**

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;

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when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or

when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

### **Pre-Release of Sanofi ADSs**

Unless we instruct the depository not to, the deposit agreement permits the depository to deliver Sanofi ADSs before deposit of the underlying shares. This is called a pre-release of the Sanofi ADSs. The depository may also deliver shares upon cancellation of pre-released Sanofi ADSs (even if the Sanofi ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depository. The depository may receive Sanofi ADSs instead of shares to close out a pre-release. Unless otherwise agreed in writing, the depository may pre-release Sanofi ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to the depository in writing that it or its customer (i) owns the shares or Sanofi ADSs to be



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deposited, (ii) assigns all beneficial rights, title and interest in such shares or ADRs to the depositary in its capacity as depositary and (iii) will not take any action with respect to such shares or ADRs that is inconsistent with the transfer of beneficial ownership, other than in satisfaction of such pre-release; (2) the pre-release must be fully collateralized with cash, U.S. government securities or other collateral that the depositary considers appropriate; (3) the depositary must be able to close out the pre-release on not more than five business days' notice; and (4) the depositary may require such further indemnities and credit regulations as it deems appropriate. In addition, the depositary will limit the number of Sanofi ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time, if it thinks it is appropriate to do so. The depositary may retain for its own account any compensation received by it in connection with the foregoing.

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**PART II**

**Item 13. Defaults, Dividend Arrearages and Delinquencies**

N/A

**Item 14. Material Modifications to the Rights of Security Holders**

N/A

**Item 15. Controls and Procedures**

(a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Sanofi was timely made known to them by others within the Group.

(b) Report of Management on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2011 based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2011 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit and Ernst & Young Audit, independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2011, which is included herein. See paragraph (c) of the present Item 15, below.

(c) See report of PricewaterhouseCoopers Audit and Ernst & Young Audit, independent registered public accounting firms, included under Item 18. Financial Statements on page F-3.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Item 16.**

[Reserved]

#### **Item 16A. Audit Committee Financial Expert**

Our Board of Directors has determined that Klaus Pohle, Robert Castaigne and Gérard Van Kemmel, directors serving on the Audit Committee, are independent financial experts within the meaning of §407 of the Sarbanes-Oxley Act of 2002. The Board of Directors deemed Klaus Pohle to be a financial expert taking into account his education and professional experience in financial matters, accountancy and internal control. The Board of Directors determined that Robert Castaigne qualifies as a financial expert based on his education and his experience as Chief Financial Officer of a major corporation. The Board of Directors determined that

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Gérard Van Kemmel qualifies as a financial expert based on his experience as a partner at an international accounting firm. The Board of Directors has also determined that Carole Piwnica possesses the requisite knowledge and experience in finance and accounting for Audit Committee membership. The Board of Directors has determined that all four directors meet the independence criteria of U.S. Securities and Exchange Commission Rule 10A-3, although only Mrs. Piwnica, Mr. Pohle and Mr. Van Kemmel meet the French AFEP-MEDEF criteria of independence applied by the Board of Directors for general corporate governance purposes. (See Item 16.G, below.)

**Item 16B. Code of Ethics**

We have adopted a financial code of ethics, as defined in Item 16B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our Website at [www.sanofi.com](http://www.sanofi.com) (information on our website is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained without charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

**Item 16C. Principal Accountants Fees and Services**

See Note E. to our consolidated financial statements included at Item 18 of this annual report.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

N/A

***E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers***

In 2011, Sanofi made the following purchases of its ordinary shares.

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(1)</sup>	(d) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs
June 2011	2,125,000	52.58	2,125,000	10,376,249,740
August 2011	5,840,822	47.96	5,840,822	10,096,123,917
September 2011	2,229,631	48.46	2,229,631	9,988,075,999
November 2011	8,094,187	48.83	8,094,187	9,592,836,847
December 2011	3,365,500	53.16	3,365,500	9,413,926,867

(1) The Company was authorized to repurchase up to 10,487,982,240 of shares for a period of eighteen months (i.e., through November 6, 2012) by the Annual Shareholders Meeting held on May 6, 2011.

This schedule does not include purchases and sales conducted by Exane under a liquidity contract entered into in 2010 and that is still in effect. For more information see Item 10.B *Memorandum and Articles of Association - Use of Share Repurchase Programs*.

**Item 16F. Change in Registrant's Certifying Accountant**

N/A

**Item 16G. Corporate Governance**

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets. In addition, we generally follow the so-called "AFEP-MEDEF" corporate governance

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recommendations for French listed issuers. As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to or in some cases, more stringent than the corresponding rules of the New York Stock Exchange. Nevertheless, there are important differences to keep in mind.

In line with New York Stock Exchange rules applicable to domestic issuers, Sanofi maintains a board of directors at least half of the members of which are independent. Sanofi evaluates the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF corporate governance recommendations as the principal reference. We believe that AFEP-MEDEF's overarching criteria for independence—no relationship of any kind whatsoever with the Company, its group or the management of either that is such as to color a Board member's judgment—are on the whole consistent with the goals of the New York Stock Exchange's rules although the specific tests proposed under the two standards may vary on some points. We note that under AFEP-MEDEF rules, our non-executive Chairman of the Board has automatically been classified as non-independent although he has no relationship with Sanofi that would cause him to be non-independent under the rules of the New York Stock Exchange. Additionally, we have complied with the audit committee independence and other requirements of the Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Compensation Committee includes non-independent members, which is permitted under the AFEP-MEDEF rules but would not be compliant with the rules of the New York Stock Exchange for domestic issuers.

Under French law, the committees of our Board of Directors are advisory only, and where the New York Stock Exchange Listed Company Manual would vest certain decision-making powers with specific committees by delegation (*e.g.*, nominating or audit committees), our Board of Directors remains under French law the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholder meeting of Sanofi that is competent to appoint our auditors upon the proposal of our Board of Directors; although our internal rules provide that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory auditors be appointed, share the New York Stock Exchange's underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option or restricted shares plans or other share capital increases, whether for the benefit of top management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France. On the other hand, there is not a tradition of non-executive Board of Director sessions. Our Audit Committee is entirely composed of independent directors as that term is defined in Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. The composition of our Audit Committee, Compensation Committee, and Appointments and Governance Committee includes directors who are also officers or recently retired officers of our principal shareholders.

As a foreign private issuer under the U.S. securities laws, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on U.S. Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on U.S. Form 10-Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between Sanofi on the one hand and its Directors and Chief Executive Officer on the other hand, which are then presented to shareholders for approval at the next annual meeting. This legal safeguard provides shareholders with an opportunity to approve

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significant aspects of the Chief Executive Officer's compensation package even in the absence of "say on pay" legislation in France, and it operates in place of certain provisions of the NYSE Listed Company Manual.

### **Item 16H. Mine Safety Disclosure**

N/A

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**PART III**

**Item 17. Financial Statements**

See Item 18.

**Item 18. Financial Statements**

See pages F-1 through F-123 incorporated herein by reference.

**Item 19. Exhibits**

- 1.1 Articles of association (statuts) of Sanofi (English translation)
- 1.2 Board Charter (Règlement Intérieur) of Sanofi (English translation)
- 2.1 Form of Deposit Agreement between Sanofi and JPMorgan Chase Bank, N.A., as depositary (*incorporated herein by reference to Exhibit A to the Registration Statement on Form F-6 dated August 7, 2007 relating to our American Depositary Shares, SEC File No. 333-145177*)
- 2.2 Amendment No.1 to Deposit Agreement between Sanofi and JPMorgan Chase Bank, N.A., as depositary (*incorporated herein by reference to Exhibit (a)(2) to Post-Effective Amendment No.1 to Form F-6 dated April 30, 2011 relating to our American Depositary Shares, SEC File No. 333-145177*)
- 2.3 Instrument defining rights of holders of American Depositary Shares each representing one quarter of a Participating Share Series A (*incorporated by reference to Item. 3 Exhibit (a) of the Registration Statement on Form F-6 (Registration No. 33-31904) dated November 21, 1989*)
- 4.1 Facilities Agreement, dated October 2, 2010, by and among Sanofi-Aventis, BNP Paribas, J.P. Morgan plc and Société Générale Corporate & Investment Banking acting as Initial Mandated Lead Arrangers, Société Générale acting as Facilities Agent, the Companies listed as Additional Borrowers thereto and the Financial Institutions included as Lenders therein. (*incorporated by reference to Exhibit (b)(A) of the Tender Offer Statement on Schedule TO filed on October 4, 2010.*)
- 4.2 Amendment dated February 15, 2011 to the Facilities Agreement, dated October 2, 2010, by and among Sanofi-Aventis, BNP Paribas, J.P. Morgan plc and Société Générale Corporate & Investment Banking acting as Initial Mandated Lead Arrangers, Société Générale acting as Facilities Agent, the Companies listed as Additional Borrowers thereto and the Financial Institutions included as Lenders therein. (*incorporated by reference to Exhibit (b)(B) of Amendment No. 15 to the Tender Offer Statement on Schedule TO filed on February 16, 2011*)
- 4.3 Agreement and Plan of Merger, dated as of February 16, 2011, among Sanofi-Aventis, GC Merger Corp., and Genzyme Corporation (*incorporated by reference to Exhibit (d)(1) of Amendment No. 15 to the Tender Offer Statement on Schedule TO filed on February 16, 2011*)
- 4.4 Form of Contingent Value Rights Agreement by and among Sanofi and Trustee (*incorporated by reference to Exhibit (d)(2) of Amendment No. 15 to the Tender Offer Statement on Schedule TO filed on February 16, 2011*)
- 8.1 List of significant subsidiaries, see Item 4. Information on the Company C. Organizational Structure of this 20-F.



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- 12.1 Certification by Christopher Viehbacher, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
- 12.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
- 13.1 Certification by Christopher Viehbacher, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 13.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 23.1 Consent of Ernst & Young Audit dated March 5, 2012
- 23.2 Consent of PricewaterhouseCoopers Audit dated March 5, 2012
- 99.1 Report of the Chairman of the Board of Directors for 2011 as required by Art. L. 225-37 paragraph 6 of the French Commercial Code

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**Signatures**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Sanofi

by: /s/ **CHRISTOPHER VIEHBACHER**  
**Christopher Viehbacher**

**Chief Executive Officer**

Date: March 5, 2012

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**ANNUAL CONSOLIDATED FINANCIAL STATEMENTS**

**The financial statements are presented in accordance with  
International Financial Reporting Standards (IFRS)**

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**REPORT OF INDEPENDENT REGISTERED  
PUBLIC ACCOUNTING FIRMS**

**SANOFI**

To the Board of Directors and Shareholders of Sanofi,

We have audited the accompanying consolidated balance sheets of Sanofi and its subsidiaries (together the Group) as of December 31, 2011, 2010 and 2009, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States), (the PCAOB). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Group as of December 31, 2011, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the PCAOB, the effectiveness of the Group's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 5, 2012 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 5, 2012

PricewaterhouseCoopers Audit

Xavier Cauchois

Ernst & Young Audit

Christian Chiarasini

Jacques Pierres

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**REPORT OF INDEPENDENT REGISTERED  
PUBLIC ACCOUNTING FIRMS**

**SANOFI**

To the Board of Directors and Shareholders of Sanofi,

We have audited internal control over financial reporting of Sanofi and its subsidiaries (together the Group ) as of December 31, 2011, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Group’s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company’s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States), (the PCAOB ). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

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We also have audited, in accordance with the standards of the PCAOB, the consolidated balance sheets of the Group as of December 31, 2011, 2010 and 2009, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2011 and our report dated March 5, 2012 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 5, 2012

PricewaterhouseCoopers Audit

Xavier Cauchois

Ernst & Young Audit

Christian Chiarasini

Jacques Pierres

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**Table of Contents****CONSOLIDATED BALANCE SHEETS**

( million)	Note	December 31, 2011	December 31, 2010	December 31, 2009
<b>ASSETS</b>				
Property, plant and equipment	<b>D.3.</b>	10,750	8,155	7,830
Goodwill	<b>D.4.</b>	38,079	31,932	29,733
Other intangible assets	<b>D.4.</b>	23,639	12,479	13,747
Investments in associates and joint ventures	<b>D.6.</b>	807	924	955
Non-current financial assets	<b>D.7.</b>	2,399	1,644	998
Deferred tax assets	<b>D.14.</b>	3,633	3,051	2,912
<b>Non-current assets</b>		<b>79,307</b>	<b>58,185</b>	<b>56,175</b>
Inventories	<b>D.9.</b>	6,051	5,020	4,444
Accounts receivable	<b>D.10.</b>	8,042	6,507	6,015
Other current assets	<b>D.11.</b>	2,401	2,000	2,104
Current financial assets	<b>D.12.</b>	173	51	277
Cash and cash equivalents	<b>D.13. - D.17.</b>	4,124	6,465	4,692
<b>Current assets</b>		<b>20,791</b>	<b>20,043</b>	<b>17,532</b>
Assets held for sale or exchange <sup>(1)</sup>	<b>D.8.</b>	67	7,036	6,544
<b>TOTAL ASSETS</b>		<b>100,165</b>	<b>85,264</b>	<b>80,251</b>

<sup>(1)</sup> The assets of Merial, classified in *Assets held for sale or exchange* in 2010 and 2009, have in 2011 been reclassified to the relevant balance sheet line items, in accordance with IFRS 5.26 (see Notes D.2. and D.8.1.).

The accompanying notes on pages F-10 to F-123 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED BALANCE SHEETS**

( million)	Note	December 31, 2011	December 31, 2010	December 31, 2009
<b>LIABILITIES &amp; EQUITY</b>				
Equity attributable to equity holders of Sanofi	<b>D.15.</b>	56,219	53,097	48,322
Equity attributable to non-controlling interests	<b>D.16.</b>	170	191	258
<b>Total equity</b>		<b>56,389</b>	<b>53,288</b>	<b>48,580</b>
Long-term debt	<b>D.17.</b>	12,499	6,695	5,961
Non-current liabilities related to business combinations and to non-controlling interests	<b>D.18.</b>	1,336	388	75
Provisions and other non-current liabilities	<b>D.19.</b>	10,346	9,326	8,236
Deferred tax liabilities	<b>D.14.</b>	6,011	3,808	4,933
<b>Non-current liabilities</b>		<b>30,192</b>	<b>20,217</b>	<b>19,205</b>
Accounts payable		3,183	2,800	2,654
Other current liabilities	<b>D.19.4.</b>	7,221	5,624	5,369
Current liabilities related to business combinations and to non-controlling interests	<b>D.18.</b>	220	98	76
Short-term debt and current portion of long-term debt	<b>D.17.</b>	2,940	1,565	2,866
<b>Current liabilities</b>		<b>13,564</b>	<b>10,087</b>	<b>10,965</b>
Liabilities related to assets held for sale or exchange <sup>(1)</sup>	<b>D.8.</b>	20	1,672	1,501
<b>TOTAL LIABILITIES &amp; EQUITY</b>		<b>100,165</b>	<b>85,264</b>	<b>80,251</b>

<sup>(1)</sup> The assets of Merial, classified in *Assets held for sale or exchange* in 2010 and 2009, have in 2011 been reclassified to the relevant balance sheet line items, in accordance with IFRS 5.26 (see Notes D.2. and D.8.1.).

The accompanying notes on pages F-10 to F-123 are an integral part of the consolidated financial statements.



**Table of Contents****CONSOLIDATED INCOME STATEMENTS**

	Note	Year ended		
		December 31, 2011	December 31, 2010 <sup>(1)</sup>	Year ended December 31, 2009 <sup>(1)</sup>
( million)				
<b>Net sales</b>	<b>D.34. - D.35.</b>	<b>33,389</b>	<b>32,367</b>	<b>29,785</b>
Other revenues		1,669	1,669	1,447
Cost of sales		(10,902)	(9,398)	(8,107)
<b>Gross profit</b>		<b>24,156</b>	<b>24,638</b>	<b>23,125</b>
Research and development expenses		(4,811)	(4,547)	(4,626)
Selling and general expenses		(8,536)	(8,149)	(7,464)
Other operating income	<b>D.25.</b>	319	369	861
Other operating expenses	<b>D.26.</b>	(315)	(292)	(481)
Amortization of intangible assets		(3,314)	(3,529)	(3,528)
Impairment of intangible assets	<b>D.5.</b>	(142)	(433)	(372)
Fair value remeasurement of contingent consideration liabilities	<b>D.18.</b>	15		
Restructuring costs	<b>D.27.</b>	(1,314)	(1,384)	(1,080)
Other gains and losses, and litigation <sup>(2)</sup>	<b>D.28.</b>	(327)	(138)	
<b>Operating income</b>		<b>5,731</b>	<b>6,535</b>	<b>6,435</b>
Financial expenses	<b>D.29.</b>	(552)	(468)	(325)
Financial income	<b>D.29.</b>	140	106	27
<b>Income before tax and associates and joint ventures</b>		<b>5,319</b>	<b>6,173</b>	<b>6,137</b>
Income tax expense	<b>D.30.</b>	(455)	(1,430)	(1,399)
Share of profit/(loss) of associates and joint ventures	<b>D.31.</b>	1,070	978	953
<b>Net income</b>		<b>5,934</b>	<b>5,721</b>	<b>5,691</b>
Attributable to non-controlling interests	<b>D.32.</b>	241	254	426
<b>Net income attributable to equity holders of Sanofi</b>		<b>5,693</b>	<b>5,467</b>	<b>5,265</b>
Average number of shares outstanding (million)	<b>D.15.9.</b>	1,321.7	1,305.3	1,305.9
Average number of shares outstanding after dilution (million)	<b>D.15.9.</b>	1,326.7	1,308.2	1,307.4
Basic earnings per share (in euros)		4.31	4.19	4.03
Diluted earnings per share (in euros)		4.29	4.18	4.03

<sup>(1)</sup> The results of operations of Meril, previously reported as held-for-exchange, have been reclassified and included in net income of continuing operations in accordance with IFRS 5.36., following the announcement that Meril and Intervet/Schering-Plough are to be maintained as two separate businesses operating independently.

<sup>(2)</sup> See Note B.20.2.

The accompanying notes on pages F-10 to F-123 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

<i>( million)</i>	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31, 2009
<b>Net income</b>	<b>5,934</b>	<b>5,721</b>	<b>5,691</b>
<i>Attributable to equity holders of Sanofi</i>	5,693	5,467	5,265
<i>Attributable to non-controlling interests</i>	241	254	426
<b>Other elements of comprehensive income:</b>			
Actuarial gains (losses)	(677)	(311)	(169)
Remeasurement of previously-held equity interests:			
Merial (50%)			1,379
Zentiva (24.9%)			108
Tax effect on above items <sup>(1)</sup>	138	172	(318)
<b>Items that may not be reclassified as income</b>	<b>(539)</b>	<b>(139)</b>	<b>1,000</b>
Available-for-sale financial assets	250	141	110
Cash flow hedges	5	17	(175)
Change in currency translation difference	(79)	2,654	(298)
Tax effect on above items <sup>(1)</sup>	4	(20)	44
<b>Items that may be reclassified as income</b>	<b>180</b>	<b>2,792</b>	<b>(319)</b>
<b>Other comprehensive income for the period, net of taxes</b>	<b>(359)</b>	<b>2,653</b>	<b>681</b>
<b>Total comprehensive income</b>	<b>5,575</b>	<b>8,374</b>	<b>6,372</b>
<i>Attributable to equity holders of Sanofi</i>	5,346	8,109	5,945
<i>Attributable to non-controlling interests</i>	229	265	427

<sup>(1)</sup> See analysis in Note D.15.7.

The accompanying notes on pages F-10 to F-123 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

( million)	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share-based payment	Other comprehensive income <sup>(1)</sup>	Attributable to equity holder of Sanofi	Attributable to non-controlling interests	Total equity
<b>Balance at January 1, 2009</b>	<b>2,631</b>	<b>44,819</b>	<b>(552)</b>	<b>1,581</b>	<b>(3,613)</b>	<b>44,866</b>	<b>205</b>	<b>45,071</b>
Other comprehensive income for the period		1,000			(320)	680	1	681
Net income for the period		5,265				5,265	426	5,691
<b>Comprehensive income for the period</b>		<b>6,265</b>			<b>(320)</b>	<b>5,945</b>	<b>427</b>	<b>6,372</b>
Dividend paid out of 2008 earnings ( 2.20 per share)		(2,872)				(2,872)		(2,872)
Payment of dividends and equivalents to non-controlling interests							(418)	(418)
Share-based payment plans:								
Exercise of stock options	6	134				140		140
Proceeds from sale of treasury shares on exercise of stock options			26			26		26
Value of services obtained from employees				114		114		114
Tax effect on the exercise of stock options				1		1		1
Non-controlling interests generated by acquisitions							49	49
Changes in non-controlling interests without loss of control							(5)	(5)
Step acquisitions		102				102		102
<b>Balance at December 31, 2009</b>	<b>2,637</b>	<b>48,448</b>	<b>(526)</b>	<b>1,696</b>	<b>(3,933)</b>	<b>48,322</b>	<b>258</b>	<b>48,580</b>
Other comprehensive income for the period		(139)			2,781	2,642	11	2,653
Net income for the period		5,467				5,467	254	5,721
<b>Comprehensive income for the period</b>		<b>5,328</b>			<b>2,781</b>	<b>8,109</b>	<b>265</b>	<b>8,374</b>
Dividend paid out of 2009 earnings ( 2.40 per share)		(3,131)				(3,131)		(3,131)
Payment of dividends and equivalents to non-controlling interests							(307)	(307)
Share repurchase program <sup>(2)</sup>			(321)			(321)		(321)
Reduction in share capital <sup>(2)</sup>	(16)	(404)	420					
Share-based payment plans:								
Exercise of stock options	1	17				18		18
Proceeds from sale of treasury shares on exercise of stock options			56			56		56
Value of services obtained from employees				133		133		133
Tax effects on the exercise of stock options								
Non-controlling interests generated by acquisitions							1	1
Changes in non-controlling interests without loss of control		(89)				(89)	(26)	(115)
<b>Balance at December 31, 2010</b>	<b>2,622</b>	<b>50,169</b>	<b>(371)</b>	<b>1,829</b>	<b>(1,152)</b>	<b>53,097</b>	<b>191</b>	<b>53,288</b>
Other comprehensive income for the period		(539)			192	(347)	(12)	(359)
Net income for the period		5,693				5,693	241	5,934
<b>Comprehensive income for the period</b>		<b>5,154</b>			<b>192</b>	<b>5,346</b>	<b>229</b>	<b>5,575</b>
Dividend paid out of 2010 earnings ( 2.50 per share)		(3,262)				(3,262)		(3,262)
Payment of dividends and equivalent to non-controlling interests							(252)	(252)
Increase in share capital dividends paid in shares <sup>(2)</sup>	76	1,814				1,890		1,890
Share repurchase program <sup>(2)</sup>			(1,074)			(1,074)		(1,074)
Reduction in share capital <sup>(2)</sup>	(21)	(488)	509					
Share-based payment plans:								
Exercise of stock options	4	66				70		70
Issuance of restricted shares	1	(1)						
Proceeds from sale of treasury shares on exercise of stock options			3			3		3

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Value of services obtained from employees				143		143		143
Tax effects on the exercise of stock options				8		8		8
Change in non-controlling interests without loss of control		(2)				(2)		2
<b>Balance at December 31, 2011</b>	<b>2,682</b>	<b>53,450</b>	<b>(933)</b>	<b>1,980</b>	<b>(960)</b>	<b>56,219</b>	<b>170</b>	<b>56,389</b>

(1) See Note D.15.7.

(2) See Notes D.15.3., D.15.4. and D.15.5.

The accompanying notes on pages F-10 to F-123 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF CASH FLOWS**

( million)	Note	Year ended December 31, 2011	Year ended December 31, 2010 <sup>(1)</sup>	Year ended December 31, 2009 <sup>(1)</sup>
<b>Net income attributable to equity holders of Sanofi</b>		<b>5,693</b>	<b>5,467</b>	<b>5,265</b>
Non-controlling interests, excluding BMS <sup>(2)</sup>		15	17	22
Share of undistributed earnings of associates and joint ventures		27	52	(19)
Depreciation, amortization and impairment of property, plant and equipment and intangible assets		5,553	5,129	5,011
Gains and losses on disposals of non-current assets, net of tax <sup>(3)</sup>		(34)	(111)	(27)
Net change in deferred taxes		(1,865)	(1,511)	(1,153)
Net change in provisions		40	461	165
Cost of employee benefits (stock options and other share-based payments)		143	133	114
Impact of the workdown of acquired inventories remeasured at fair value		476	142	90
Unrealized (gains)/losses recognized in income		(214)	245	(84)
<b>Operating cash flow before changes in working capital</b>		<b>9,834</b>	<b>10,024</b>	<b>9,384</b>
(Increase)/decrease in inventories		(232)	(386)	(469)
(Increase)/decrease in accounts receivable		(257)	(96)	(395)
Increase/(decrease) in accounts payable		(87)	59	(324)
Net change in other current assets, current financial assets and other current liabilities		61	258	406
<b>Net cash provided by/(used in) operating activities <sup>(4)</sup></b>		<b>9,319</b>	<b>9,859</b>	<b>8,602</b>
Acquisitions of property, plant and equipment and intangible assets	<b>D.3. - D.4.</b>	(1,782)	(1,662)	(1,826)
Acquisitions of investments in consolidated undertakings, net of cash acquired	<b>D.1.</b>	(13,590)	(1,659)	(5,563)
Acquisitions of available-for-sale financial assets	<b>D.7.</b>	(26)	(74)	(5)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax <sup>(5)</sup>	<b>D.1.3.</b>	359	136	87
Net change in loans and other financial assets		338	(216)	(20)
<b>Net cash provided by/(used in) investing activities</b>		<b>(14,701)</b>	<b>(3,475)</b>	<b>(7,327)</b>
Issuance of Sanofi shares <sup>(6)</sup>	<b>D.15.</b>	70	18	142
Dividends paid:				
to shareholders of Sanofi <sup>(6)</sup>		(1,372)	(3,131)	(2,872)
to non-controlling interests, excluding BMS <sup>(2)</sup>		(17)	(7)	(6)
Transactions with non-controlling interests, other than dividends			(97)	
Additional long-term debt contracted	<b>D.17.</b>	8,359	505	4,697
Repayments of long-term debt	<b>D.17.</b>	(2,931)	(1,984)	(1,989)
Net change in short-term debt		(145)	314	(786)
Acquisition of treasury shares	<b>D.15.4.</b>	(1,074)	(321)	
Disposals of treasury shares, net of tax	<b>D.15.</b>	3	57	26
<b>Net cash provided by/(used in) financing activities</b>		<b>2,893</b>	<b>(4,646)</b>	<b>(788)</b>
<b>Impact of exchange rates on cash and cash equivalents</b>		<b>1</b>	<b>55</b>	<b>27</b>
<b>Impact of Merial cash and cash equivalents <sup>(1)</sup></b>	<b>D.8.1.</b>	<b>147</b>		
<b>Net change in cash and cash equivalents</b>		<b>(2,341)</b>	<b>1,793</b>	<b>514</b>
<b>Cash and cash equivalents, beginning of period</b>		<b>6,465</b>	<b>4,692</b>	<b>4,226</b>
<b>Cash and cash equivalents, end of period</b>	<b>D.13.</b>	<b>4,124</b>	<b>6,465</b>	<b>4,692</b>
<sup>(1)</sup> Further to the announcement that Merial and Intervet/Schering-Plough are to be maintained as separate businesses operating independently, the line items in the statement of cash flows for the comparative periods (2010 and 2009) include cash flows generated by the operating investing and financing activities of Merial. The cash and cash equivalents of Merial were reported in the balance sheet in Assets held for sale or exchange as of December 31, 2009 and 2010.				
Net change in cash and cash equivalents excluding Merial			1,773	466
Net change in cash and cash equivalents of Merial			20	48
Net change in cash and cash equivalents including Merial			1,793	514
<sup>(2)</sup> See note C.1.				
<sup>(3)</sup> Including available-for-sale financial assets.				
<sup>(4)</sup> Including:				
Income tax paid		(2,815)	(3,389)	(3,019)
Interest paid		(447)	(475)	(269)

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Interest received	100	62	88
Dividends received from non-consolidated entities	7	3	5

<sup>(5)</sup> *Property, plant and equipment, intangible assets, investments in consolidated entities and other non-current financial assets.*

<sup>(6)</sup> *The amounts for the capital increase and dividends paid to equity holders of Sanofi are presented net of the amount of the dividends paid in shares; this payment does not result in a financial flow.*

The accompanying notes on pages F-10 to F-123 are an integral part of the consolidated financial statements.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

***INTRODUCTION***

Sanofi and its subsidiaries ( Sanofi or the Group ) is a diversified global healthcare leader engaged in the research, development and marketing of therapeutic solutions focused on patient needs. Sanofi has fundamental strengths in the healthcare field, operating via six growth platforms: Emerging Markets, Diabetes Solutions, Human Vaccines, Consumer Health Care (CHC), Animal Health and Innovative Products. Sanofi, the parent company, is a *société anonyme* (a form of limited liability company) incorporated under the laws of France. The registered office is at 54, rue La Boétie, 75008 Paris, France.

Sanofi is listed in Paris (Euronext: SAN) and New York (NYSE: SNY).

The consolidated financial statements for the year ended December 31, 2011, and the notes thereto, were adopted by the Sanofi Board of Directors on February 7, 2012.

***A. BASIS OF PREPARATION***

**A.1. International Financial Reporting Standards (IFRS)**

The consolidated financial statements cover the twelve-month periods ending December 31, 2011, 2010 and 2009.

In accordance with Regulation No. 1606/2002 of the European Parliament and Council of July 19, 2002 on the application of international accounting standards, Sanofi has presented its consolidated financial statements in accordance with IFRS since January 1, 2005. The term IFRS refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (SIC and IFRIC), mandatorily applicable as of December 31, 2011.

The consolidated financial statements of Sanofi as of December 31, 2011 have been prepared in compliance with IFRS as issued by the International Accounting Standards Board (IASB) and with IFRS endorsed by the European Union as of December 31, 2011.

IFRS endorsed by the European Union as of December 31, 2011 are available under the heading IAS/IFRS, Standards and Interpretations via the following web link:

[http://ec.europa.eu/internal\\_market/accounting/ias/index\\_en.htm](http://ec.europa.eu/internal_market/accounting/ias/index_en.htm)

The consolidated financial statements have been prepared in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality, and aggregation.

New standards, amendments and interpretations applicable in 2011 with an impact on the consolidated financial statements are described in Note A.2. For standards, amendments and interpretations issued by the IASB that are not mandatorily applicable in 2011, refer to Note B.28.

**A.2. New standards, amendments and interpretations applicable in 2011**

In June 2011, the IASB issued an amendment to IAS 1 (Presentation of Financial Statements). The amendment, which has mandatory application for annual periods beginning on or after July 1, 2012, has not yet been endorsed by the European Union, but it may nonetheless be applied provided that it does not contradict existing standards. This amendment requires that components of other comprehensive income that can be reclassified to the income statement be reported separately from those that cannot. The Group presents the information required by this amendment in the consolidated statement of comprehensive income as of December 31, 2011.



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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The other standards, amendments to standards and interpretations issued by the IASB with mandatory application for the Group as from the 2011 fiscal year are listed below. None of these texts has an impact on the consolidated financial statements of the Group:

May 2010 Improvements to IFRS.

Amendment to IAS 24 (Related Party Disclosures) which specifies the disclosures required for future commitments with regard to particular event occurs and relative to related parties. The Group already discloses such information.

Amendment to IAS 32 (Financial Instruments: Presentation), relative to the classification of subscription rights in a currency other than the issuer's functional currency.

Amendment to IFRIC 14, (IAS 19 – The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction: Advance payments of minimum funding requirements).

**A.3. Use of estimates**

The preparation of financial statements requires management to make reasonable estimates and assumptions, based on information available at the date of preparation of the financial statements, that may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and disclosures of contingent assets and contingent liabilities.

Examples include:

amounts deducted from sales for projected sales returns, chargeback incentives, rebates and price reductions (see Notes B.14. and D.23.);

impairment of property, plant and equipment, goodwill, intangible assets, and investments in associates and joint ventures (see Notes B.6. and D.5.);

the valuation of goodwill and the valuation and useful life of acquired intangible assets (see Notes B.3. and B.4.3., D.4. and D.5.);

the amount of post-employment benefit obligations (see Note B.23. and D.19.1.);

the amount of provisions for restructuring, litigation, tax risks and environmental risks (see Notes B.12. and D.19.);

provisions relating to product liability claims (see Notes B.12. and D.22.);

the measurement of contingent considerations (see Notes B.3. and D.18.).

Actual results could differ from these estimates.

## ***B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES***

### **B.1. Basis of consolidation**

In accordance with IAS 27 (Consolidated and Separate Financial Statements), the consolidated financial statements include the accounts of the Sanofi parent company and those of its subsidiaries, using the full consolidation method. Subsidiaries are entities which the Group controls (i.e. it has the power to govern their financial and operating activities). The existence of effectively exercisable or convertible potential voting rights is taken into account in determining whether control exists. Control is presumed to exist where the Group holds more than 50% of an entity's voting rights.

Equity interests in entities are consolidated from the date on which exclusive control of the entity is obtained; divested equity interests are deconsolidated on the date on which exclusive control ceases. The Group's share of post-acquisition profits or losses is taken to the income statement, while post-acquisition movements in the acquiree's reserves are taken to consolidated reserves.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Entities over which Sanofi exercises joint control are known as joint ventures and are accounted for using the equity method in accordance with the option in IAS 31 (Interests in Joint Ventures).

Entities over which Sanofi exercises significant influence are accounted for by the equity method in accordance with IAS 28 (Investments in Associates). Significant influence exists where Sanofi has the power to participate in the financial and operating policy decisions of the investee, but without the power to exercise control or joint control over those policies. Significant influence is presumed to exist where the Group owns directly or indirectly via its subsidiaries, between 20% and 50% of the voting rights of the investee.

Acquisition-related costs are included as a component of the cost of acquiring joint ventures and associates.

Material transactions between consolidated companies are eliminated, as are intragroup profits.

**B.2. Foreign currency translation**

**B.2.1. Accounting for transactions in foreign currencies in individual company accounts**

Non-current assets (other than receivables) and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the acquisition date.

Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the balance sheet date. The resulting gains and losses are recorded in the income statement. However, foreign exchange gains and losses arising from the translation of advances between consolidated subsidiaries for which settlement is neither planned nor likely to occur in the foreseeable future are recognized directly in equity in *Currency translation difference*.

**B.2.2. Foreign currency translation of the financial statements of foreign subsidiaries**

Sanofi reports its consolidated financial statements in euros (€).

In accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), each Group subsidiary translates foreign currency transactions into the currency that is most representative of its economic environment (the functional currency).

All assets and liabilities are translated into euros using the exchange rate of the subsidiary's functional currency prevailing at the balance sheet date. Income statements are translated using a weighted average exchange rate for the period. The resulting currency translation difference is recognized as a separate component of equity in the consolidated statement of comprehensive income, and is recognized in the income statement only when the subsidiary is sold or is wholly or partially liquidated.

Under the exemptions allowed by IFRS 1, Sanofi Group elected to eliminate, through equity, all currency translation differences for foreign operations at the January 1, 2004 IFRS transition date.

### **B.3. Business combinations and transactions with non-controlling interests**

#### **B.3.1. Accounting for business combinations, transactions with non-controlling interests and loss of control**

Business combinations are accounted for using the acquisition method. Under this method, the acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 are measured initially at their fair values as at the date of acquisition, except for non-current assets classified as held for sale (which are measured at fair value less costs to sell) and except for assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Restructuring liabilities are recognized as a liability of the acquiree only if the acquiree has an obligation as of the acquisition date to carry out the restructuring.

Business combinations, completed on or after January 1, 2010, are accounted for in accordance with the revised IFRS 3 (Business Combinations) and the amended IAS 27 (Consolidated and Separate Financial Statements). These revised standards are applied prospectively.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The principal accounting rules applicable to business combinations and transactions with non-controlling interests include:

Acquisition-related costs are recognized as an expense on the acquisition date, as a component of *Operating income*. In the case of business combinations completed before January 1, 2010, these costs were accounted for as a component of the cost of the acquisition.

Contingent consideration is recognized in equity if the contingent payment is settled by delivery of a fixed number of the acquirer's equity instruments; in all other cases, it is recognized in liabilities related to business combinations. Contingent consideration is recognized at fair value at the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a liability, its adjustments are recognized in profit or loss, on the *Fair value remeasurement of contingent consideration liabilities* line except if such adjustments are made 12 months later and are related to facts and circumstances existing as at the acquisition date. Subsequent contingent consideration adjustments in respect of business combinations completed before January 1, 2010 continue to be accounted for in accordance with the pre-revision IFRS 3 (i.e. through goodwill).

In the case of business combinations completed before January 1, 2010, where the contractual arrangements for the combination included an adjustment to the cost of the combination contingent upon future events, this adjustment was included in the cost of the combination at the acquisition date, if the adjustment was probable and could be measured reliably. If the adjustment was not probable or could not be measured reliably, it was not included in the cost of the combination on initial recognition of the combination. If the adjustment subsequently became probable and reliably measurable, the additional consideration was treated as an adjustment to the cost of the combination (i.e. as an adjustment to goodwill).

In the case of a step acquisition, the previously-held equity interest in the acquiree is remeasured at its acquisition-date fair value, with the difference between this fair value and the carrying amount taken to profit or loss, along with any gains or losses relating to the previously-held interest that were recognized in other comprehensive income and which are reclassifiable to profit or loss.

In the case of business combinations where control was acquired in stages before January 1, 2010, goodwill was determined at each stage as the excess of the cost of the transaction over the fair value of the share of assets acquired in each transaction. The remeasurement of the fair value of the previously-held equity interest was recognized in equity on the line *Remeasurement of previously-held equity interests*.

Goodwill may be calculated on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option may be elected for each acquisition individually. For business combinations completed before January 1, 2010, goodwill was in all cases calculated on the basis of a share of the fair value of the acquiree proportionate to the interest acquired.

The effects of (i) a buyout of non-controlling interests in a subsidiary already controlled by the Group, and (ii) divestment of a percentage interest without loss of control, are recognized in equity.

In a partial disposal resulting in loss of control, the retained equity interest is remeasured at fair value at the date of loss of control; the gain or loss recognized on the disposal will include the effect of this remeasurement and the gain or loss on the sale of the equity interest, including items initially recognized in equity and reclassified to profit or loss.

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Adjustments to the values of assets and liabilities initially determined provisionally (pending the results of independent valuations or further analysis) are recognized as a retrospective adjustment to goodwill if they are made within twelve months of the acquisition date. Once this twelve-month period has elapsed, the effects of any adjustments are recognized directly in the income statement, unless they qualify as an error correction.

Under the exemptions allowed by IFRS 1, Sanofi Group elected not to restate in accordance with IFRS 3 any business combinations completed prior to the January 1, 2004 transition date. This includes the combination between Sanofi and Synthélabo that took place in 1999.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. Moreover, the revised IFRS 3 does not specify the accounting treatment of contingent consideration related to a business combination made by an entity prior to the acquisition of control in that entity and recognized as a liability in its balance sheet. The accounting treatment applied by the Group to such liability is to measure it at fair value as of the acquisition date and to report it in the line item ***Liabilities related to business combinations and to non-controlling interests***. This treatment is consistent with that applied to contingent consideration in the books of the acquirer.

**B.3.2. Goodwill**

The excess of the cost of an acquisition over the Group's interest in the fair value of the identifiable assets and liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown as a separate line in the balance sheet in intangible assets under ***Goodwill***, whereas goodwill arising on the acquisition of associates and joint ventures is recorded in ***Investments in associates and joint ventures***.

Goodwill arising on the acquisition of foreign entities is measured in the functional currency of the acquired entity and translated using the exchange rate prevailing at the balance sheet date.

In accordance with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment (see Note B.6.).

Goodwill is tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes liable to have an other-than-temporary impact on the substance of the original investment.

**B.4. Other intangible assets**

Intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as at the date of the combination. They are amortized on a straight line basis over their useful lives.

The useful lives of intangible assets are reviewed at each reporting date. The effect of any adjustment to useful lives is recognized prospectively as a change of accounting estimate.

Amortization of intangible assets is recognized in the income statement under *Amortization of intangible assets* with the exception of amortization of acquired or internally-developed software, which is recognized on the relevant line of the income statement according to the purpose for which the software is used.

The Group does not own any intangible assets with an indefinite useful life (other than goodwill).

Intangible assets are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

#### **B.4.1. Research and development not acquired in a business combination**

Internally generated research and development

In accordance with IAS 38 (Intangible Assets), internally generated research expenditure is expensed as incurred under *Research and development expenses*.

Under IAS 38, internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of completing the



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development project; (b) the Group's intention to complete the project; (c) the Group's ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are considered not to have been met until marketing approval has been obtained from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are expensed as incurred under *Research and development expenses*.

Chemical industrial development expenses incurred to develop a second-generation process are incurred after initial regulatory approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as being met, these expenses are capitalized under *Other intangible assets* as incurred.

#### Separately acquired research and development

Payments for separately acquired research and development are capitalized under *Other intangible assets* provided that they meet the definition of an intangible asset: a resource that is (i) controlled by the Group, (ii) expected to provide future economic benefits, and (iii) identifiable (i.e. is either separable or arises from contractual or legal rights). Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits will flow to the entity) is considered to be satisfied for separately acquired research and development. Because the amount of the payments is determinable, the second condition for capitalization (the cost can be measured reliably) is also met. Consequently, upfront and milestone payments to third parties related to pharmaceutical products for which regulatory marketing approval has not yet been obtained are recognized as intangible assets, and amortized on a straight line basis over their useful lives from the date on which regulatory approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases and payments made to purchase generics files are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services and continuous payments under research and development collaborations, unrelated to the outcome of the research and development efforts, are expensed over the service term.

#### **B.4.2. Intangible assets not acquired in a business combination**

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives for the Group (three to five years).

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Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 criteria for recognition as an intangible asset are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

### **B.4.3. Intangible assets acquired in a business combination**

Intangible assets acquired in a business combination which relate to in-process research and development and are reliably measurable are separately identified from goodwill and capitalized in *Other intangible assets* in accordance with IFRS 3 (Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of regulatory approval.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Rights to products sold by the Group are amortized on a straight line basis over their useful lives, determined on the basis of cash flow forecasts that take account of, among other factors, the period of legal protection of the related patents.

**B.5. Property, plant and equipment**

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as at the date of the combination. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets, unless (i) it is probable that future economic benefits associated with these costs will flow to the Group, and (ii) the costs can be measured reliably.

Day-to-day maintenance costs of property, plant and equipment are expensed as incurred.

Borrowing costs attributable to the financing of items of property, plant and equipment, and incurred during the construction period of such items, are capitalized as part of the acquisition cost of the item.

Government grants relating to non-current assets are deducted from the acquisition cost of the asset to which they relate.

In accordance with IAS 17, Leases, items of property, plant and equipment, leased by Sanofi as lessee under finance leases, are recognized as an asset in the balance sheet, with the related lease obligation recognized as a liability. A lease qualifies as a finance lease if it transfers substantially all the risks and rewards of ownership of the asset to the Group. Assets held under finance leases are carried at the lower of the fair value of the leased asset or the present value of the minimum lease payments, and are depreciated over the shorter of the useful life of the asset or the term of the lease.

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Plant and equipment	5 to 15 years
Other tangible assets	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change of accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

## **B.6. Impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures**

### **B.6.1. Impairment of property, plant and equipment and intangible assets**

Assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment in accordance with IAS 36 (Impairment of Assets), when events or changes in circumstances indicate that the asset or CGU may be impaired.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Under IAS 36, each CGU to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria. Consequently, the CGUs used by the Group to test goodwill for impairment correspond to the geographical sub-segments of each operating segment.

Quantitative and qualitative indications of impairment (primarily relating to pharmacovigilance, patent litigation and the launch of competing products) are reviewed at each reporting date. If there is any internal or external indication of impairment, the Group estimates the recoverable amount of the asset or CGU.

Intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. These assets are not amortized.

When there is an internal or external indication of impairment, the Group estimates the recoverable amount of the asset and recognizes an impairment loss when the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine the value in use, the Group uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of medium-term plans.

In the case of goodwill, estimates of future cash flows are based on a five-year strategic plan plus an extrapolation of the cash flows beyond the five-year plan, plus a terminal value. In the case of other intangible assets, the period used is based on the economic life of the asset.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by Sanofi of the time value of money, the risks specific to the asset or CGU, and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

Impairment losses on intangible assets are recognized under *Impairment of intangible assets* in the income statement.

**B.6.2. Impairment of investments in associates and joint ventures**

In accordance with IAS 28 (Investments in Associates), the Group applies the criteria specified in IAS 39 (Financial Instruments: Recognition and Measurement), to determine whether an investment in an associate or joint venture may be impaired (see Note B.8.2.). If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in *Share of profit/loss of associates and joint ventures*.

**B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments in associates and joint ventures**

At each reporting date, the Group assesses if events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment in an associate or joint venture can be reversed. If this is the case, and the recoverable amount as determined based on the new estimates exceeds the carrying amount of the asset, the Group reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.

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Reversals of impairment losses in respect of intangible assets are recognized in the income statement under *Impairment of intangible assets*, while reversals of impairment losses in respect of investments in associates and joint ventures are recognized in the income statement under *Share of profit/loss of associates and joint ventures*. Impairment losses taken against goodwill are never reversed, unless the goodwill is part of the carrying amount of an investment in an associate or joint venture.

**B.7. Assets held for sale or exchange**

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets must be classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term *sale* also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

the appropriate level of management must be committed to a plan to sell;

an active program to locate a buyer and complete the plan must have been initiated;

the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;

completion of the sale should be foreseeable within the twelve months following the date of classification as held for sale or exchange; and

actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before the initial classification of the non-current asset (or asset group) as *held for sale or exchange*, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to classification as *held for sale or exchange*, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been classified as *held for sale or exchange*, it is no longer depreciated or amortized.

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In a disposal of an equity interest leading to loss of control, all the assets and liabilities of the entity involved are classified as assets or liabilities held for sale in the balance sheet line items *Assets held for sale or exchange* or *Liabilities related to assets held for sale or exchange*, provided that the disposal satisfies the IFRS 5 classification criteria.

The profit or loss generated by a held-for-sale asset group is reported on a separate line in the income statement for the current period and for the comparative periods presented, provided that the asset group:

represents a separate major line of business or geographical area of operations; or,

is part of a single co-ordinated plan to dispose of a separate major line of business or geographical area of operations; or,

is a subsidiary acquired exclusively with a view to resale.

Events or circumstances beyond the Group's control may extend the period to complete the sale or exchange beyond one year without precluding classification of the asset (or disposal group) in *Assets held for sale or exchange* provided that there is sufficient evidence that the Group remains committed to the planned sale or exchange.



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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Finally, in the event of changes to a plan of sale that require an asset no longer to be classified as held for sale, IFRS 5 specifies the following treatment:

The assets and liabilities previously classified as held for sale are reclassified to the appropriate balance sheet line items, with no restatement of comparative periods;

Each asset is measured at the lower of:

- (a) its carrying amount before the asset was classified as held for sale, adjusted for any depreciation, amortization or reevaluation that would have been recognized if the asset had not been classified as held for sale; or
- (b) its recoverable amount at the date of the reclassification.

The backlog of depreciation, amortization and impairment not recognized while non-current assets were classified as held for sale must be reported in the same income statement line item as that used to report impairment losses that may arise on the classification of assets as held for sale and gains or losses on the sale of such assets. In the consolidated income statement, these impacts are reported in the line item *Other gains and losses, and litigation*.

The net income of a business that was previously classified as to be discontinued or held-for-exchange and reported on a separate line in the income statement must be reclassified and included in net income from continuing operations, for all periods reported.

In addition, segment information as reported in the notes to the financial statements in accordance with IFRS 8 (Operating Segments) and relating to the income statement and the statement of cash flows (acquisitions of non-current assets) must also be restated for all prior periods reported.

**B.8. Financial instruments**

**B.8.1. Non-derivative financial assets**

Under IFRS, and in accordance with IAS 39 and IAS 32 (Financial Instruments: Presentation), Sanofi has adopted the following classification for non-derivative financial assets, based on the type of asset and on management intent at the date of initial recognition (except for assets already held at the transition date and reclassified at that date in accordance with IFRS 1). The designation and classification of such financial assets are subsequently reassessed at each reporting date.

Non-derivative financial assets are recognized on the date when Sanofi becomes party to the contractual terms of the asset. On initial recognition, financial assets are measured at fair value, plus direct transaction costs in the case of financial assets not designated as fair value

through profit or loss.

Classification, presentation and subsequent measurement of non-derivative financial assets are as follows:

Financial assets at fair value through profit or loss

These assets are classified in the balance sheet in the line items *Non-current financial assets*, *Current financial assets* and *Cash and cash equivalents*.

Financial assets at fair value through profit or loss comprise assets held for trading (financial assets acquired principally for the purpose of reselling them in the near term, usually within less than 12 months), and financial instruments designated as fair value through profit and loss on initial recognition in accordance with the conditions for application of the fair value option.

These financial assets are carried at fair value, without any deduction for transaction costs that may be incurred on sale. Realized and unrealized gains and losses resulting from changes in the fair value of these assets are recognized in the income statement, in *Financial income* or *Financial expenses*.

Realized and unrealized foreign exchange gains and losses on financial assets in currencies other than the euro are recognized in the income statement in *Financial income* or *Financial expenses*.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Available-for-sale financial assets

Available-for-sale financial assets are non-derivative financial assets that are (i) designated by management as available-for-sale or (ii) not classified as financial assets at fair value through profit or loss, held-to-maturity investments or loans and receivables. This category includes participating interests in quoted or unquoted companies (other than investments in associates and joint ventures) that management intends to hold on a long-term basis. Available-for-sale financial assets are classified in *Non-current financial assets*.

Available-for-sale financial assets are measured at fair value, without any deduction for transaction costs that may be incurred on sale. Gains and losses arising from changes in the fair value of these assets, including unrealized foreign exchange gains and losses, are recognized directly in equity in the consolidated statement of comprehensive income in the period in which they occur, except for impairment losses and foreign exchange gains and losses on debt instruments. On derecognition of an available-for-sale financial asset, or on recognition of an impairment loss on such an asset, the cumulative gains and losses previously recognized in equity are recognized in the income statement for the period under *Financial income* or *Financial expenses*.

Interest income and dividends on equity instruments are recognized in the income statement under *Financial income* when the Group is entitled to receive payment.

Available-for-sale financial assets in the form of participating interests in companies not quoted in an active market are measured at cost if their fair value cannot be measured reliably; an impairment loss is recognized when there is objective evidence that such an asset is impaired.

Realized foreign exchange gains and losses are recognized in the income statement under *Financial income* or *Financial expenses*.

Held-to-maturity investments

Held-to-maturity investments are non-derivative financial assets with fixed or determinable payments and fixed maturities that the Group has the positive intention and ability to hold to maturity.

These investments are measured at amortized cost using the effective interest method.

Sanofi did not hold any such investments during the years ending December 31, 2011, 2010 or 2009.

Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are presented in current assets, under *Other current assets* in the case of loans and under *Accounts receivable* in the case of receivables. Loans with a maturity of more than 12 months are presented in Long-term loans and advances under *Non-current financial assets*. Loans and receivables are measured at amortized cost using the effective interest method.

Realized and unrealized foreign exchange gains and losses are recognized in the income statement under *Financial income* or *Financial expenses*.

#### **B.8.2. Impairment of non-derivative financial assets**

Indicators of impairment are reviewed for all non-derivative financial assets at each reporting date. Such indicators include default in contractual payments, significant financial difficulties of the issuer or debtor, probability of bankruptcy, or prolonged or significant decline in quoted market price. An impairment loss is recognized in the income statement if there is objective evidence of impairment resulting from one or more events after the initial recognition of the asset (a loss-generating event ) and this loss-generating event has an impact on the estimated future cash flows of the financial asset or of a group of financial assets, which can be reliably estimated.

The impairment loss on loans and receivables, which are measured at amortized cost, is the difference between the carrying amount of the asset and the present value of estimated future cash flows discounted at the financial asset's original effective interest rate.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

When an impairment loss is identified on an available-for-sale financial asset, the cumulative losses previously recognized directly in equity are recorded in the income statement. The loss recognized in the income statement is the difference between the acquisition cost (net of principal repayment and amortization) and the fair value at the time of impairment, less any impairment loss previously recognized in the income statement.

The impairment loss on investments in companies, that are not quoted in an active market and are measured at cost, is the difference between the carrying amount of the investment and the present value of its estimated future cash flows, discounted at the current market interest rate for similar financial assets.

Impairment losses in respect of loans are recognized under *Financial expenses* in the income statement.

Impairment losses in respect of trade receivables are recognized under *Selling and general expenses* in the income statement.

Impairment losses on investments in companies that are not quoted in an active market and are measured at cost, and on equity instruments classified as available-for-sale financial assets, cannot be reversed through the income statement.

**B.8.3. Derivative instruments**

Derivative instruments that do not qualify for hedge accounting are initially and subsequently measured at fair value, with changes in fair value recognized in the income statement in *Other operating income* or in *Financial income* or *Financial expenses* depending on the nature of the underlying economic item which they are intended to hedge.

Derivative instruments that qualify for hedge accounting are measured in accordance with the hedge accounting requirements of IAS 39 (see Note B.8.4.).

**B.8.4. Hedging**

Hedging involves the use of derivative financial instruments. Changes in the fair value of these instruments are intended to offset the exposure of the hedged items to changes in fair value.

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As part of its overall interest rate risk and foreign exchange risk management policy, the Group enters into various transactions involving derivative instruments. Derivative instruments used in connection with the Group's hedging policy may include forward exchange contracts, currency options, interest rate swaps and interest rate options.

Derivative financial instruments qualify as hedging instruments for hedge accounting purposes when (a) at the inception of the hedge there is formal designation and documentation of the hedging relationship and of the risk management strategy and objective; (b) the hedge is expected by management to be highly effective in offsetting the risk; (c) the forecast transaction being hedged is highly probable and presents an exposure to variations in cash flows that could ultimately affect profit or loss; (d) the effectiveness of the hedge can be reliably measured; and (e) the hedge is assessed on an ongoing basis and determined actually to have been highly effective throughout the reporting periods for which the hedge was designated.

These criteria are applied when the Group uses derivative instruments designated as a fair value hedge, a cash flow hedge or a hedge of a net investment in a foreign operation.

### Fair value hedge

A fair value hedge is a hedge of the exposure to changes in fair value of a recognized asset or liability or unrecognized firm commitment that could affect profit or loss.

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged risk are recognized in the income statement, under ***Other operating income*** for hedges of operating activities and under ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

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Cash flow hedge

A cash flow hedge is a hedge of the exposure to variability in cash flows attributable to a particular risk associated with a recognized asset or liability, or a highly probable forecast transaction, which could affect profit or loss.

Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement under *Other operating income* for hedges of operating activities, and under *Financial income* or *Financial expenses* for hedges of investing or financing activities.

Cumulative changes in fair value of the hedging instrument previously recognized in equity are transferred to the income statement when the hedged transaction affects profit or loss. These transferred gains and losses are recorded under *Other operating income* for hedges of operating activities and *Financial income* or *Financial expenses* for hedges of investing or financing activities.

When a forecast transaction results in the recognition of a non-financial asset or liability, cumulative changes in the fair value of the hedging instrument previously recognized in equity are included in the initial measurement of the asset or liability.

When the hedging instrument expires or is sold, terminated or exercised, the cumulative gain or loss previously recognized in equity remains separately recognized in equity until the forecast transaction occurs. However, if the Group no longer expects the forecast transaction to occur, the cumulative gain or loss previously recognized in equity is recognized immediately in the income statement.

Hedge of a net investment in a foreign operation

In the case of a hedge of a net investment in a foreign operation, changes in the fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement under *Financial income* or *Financial expenses*. When the investment in the foreign operation is sold, the changes in the fair value of the hedging instrument previously recognized in equity are transferred to the income statement under *Financial income* or *Financial expenses*.

Discontinuation of hedge accounting

Hedge accounting is discontinued when (a) the hedging instrument expires or is sold, terminated or exercised, or (b) the hedge no longer meets the criteria for hedge accounting, or (c) the Group revokes the hedge designation, or (d) management no longer expects the forecast transaction to occur.

**B.8.5. Non-derivative financial liabilities**

Borrowings and debt

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs.

Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized under *Financial expenses* in the income statement over the term of the debt using the effective interest method.

Liabilities related to business combinations and to non-controlling interests

Liabilities related to business combinations and to non-controlling interests are split into a current portion and a non-current portion. These line items are used to recognize contingent consideration payable in business combinations (see Note B.3.1. for a description of the relevant accounting policy), and the fair value of put options granted to non-controlling interests.



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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Other non-derivative financial liabilities

Other non-derivative financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

**B.8.6. Fair value of financial instruments**

Under IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a fair value hierarchy with the following levels:

Level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);

Level 2: quoted prices in active markets for similar assets and liabilities, and valuation techniques in which all important inputs are derived from observable market data; and

Level 3: valuation techniques in which not all important inputs are derived from observable market data.

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The table below sets forth the principles used to measure the fair value of the principal financial assets and liabilities recognized by the Group in its consolidated balance sheet:

Note	Type of financial instrument	Measurement principle applied in the consolidated balance sheet	Level in the IFRS 7 fair value hierarchy as disclosed in the notes to the consolidated financial statements	Method used to determine fair value as disclosed in the notes to the consolidated financial statements			
				Valuation model	Exchange rate	Interest rate	Volatility
D.7.	Available-for-sale financial assets (quoted equity securities)	Fair value	1	Quoted market price		N/A	
D.7.	Available-for-sale financial assets (unquoted debt securities)	Fair value	2	Present value of future cash flows	N/A	Mid swap + z-spread for bonds of comparable risk and maturity	N/A
D.7.	Long-term loans and advances	Amortized cost	N/A	The amortized cost of long-term loans and advances at the balance sheet date is not materially different from their fair value.			
D.7.	Assets recognized under the fair value option <sup>(1)</sup>	Fair value	1	Market value (net asset value)		N/A	
D.20.	Forward currency contracts	Fair value	2	Present value of future cash flows	ECB Fixing	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	N/A
				Options with no knock-out feature:			
D.20.	Currency options	Fair value	2	Garman & Kohlhagen	ECB Fixing	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	Mid in-the-money
				Knock-out options: Merton, Reiner & Rubinstein			
D.20.	Interest rate swaps	Fair value	2	Present value of future cash flows	N/A	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon	N/A
D.20.	Cross-currency swaps	Fair value	2	Present value of future cash flows	ECB Fixing	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon	N/A
D.13.	Investments in collective investment schemes	Fair value	1	Market value (net asset value)		N/A	
D.13.	Negotiable debt instruments, commercial	Amortized cost	N/A	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements.			

papers, sight  
deposits and term  
deposits

<b>D.17.</b>	Financial liabilities	Amortized cost <sup>(2)</sup>	N/A	For financial liabilities with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements.	For financial liabilities with a maturity of more than 3 months, fair value as disclosed in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the balance sheet date (quoted instruments) or by discounting the future cash flows based on observable market data at the balance sheet date (unquoted instruments).
<b>D.18.</b>	Liabilities related to business combinations and to non-controlling interests (CVR)	Fair value	1	Quoted market price	N/A
<b>D.18.</b>	Liabilities related to business combinations and to non-controlling interests (except CVR)	Fair value <sup>(3)</sup>	3	Contingent consideration payable in a business combination is a financial liability under IAS 32. The fair value of such liabilities is determined by adjusting the contingent consideration at the balance sheet date using the method described in Note D.18.	

<sup>(1)</sup> These assets are held to fund a deferred compensation plan offered to certain employees, included in the obligations described in Note D.19.1.

<sup>(2)</sup> In the case of financial liabilities designated as hedged items in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value relating to the hedged risk(s).

<sup>(3)</sup> In the case of business combinations completed prior to the application of the revised IFRS 3, contingent consideration is recognized when payment becomes probable (see Note B.3.1.).

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The other financial assets and liabilities included in the Group balance sheet are the following:

Non-derivative current financial assets and liabilities: due to their short-term maturity, the fair value of these instruments approximates their carrying amount (i.e., historical cost less any credit risk allowance).

Investments in equity instruments not quoted in an active market whose fair value cannot be measured reliably are measured at amortized cost in accordance with IAS 39.

**B.8.7. Derecognition of financial instruments**

Sanofi derecognizes financial assets when the contractual rights to cash flows from these assets have ended or have been transferred and when the Group has transferred substantially all risks and rewards of ownership of these assets. If the Group has neither transferred nor retained substantially all the risks and rewards of ownership of these assets, they are derecognized if the Group does not retain the control of these assets.

Financial liabilities are derecognized when the Group's contractual obligations in respect of such liabilities are discharged or cancelled or expired.

**B.8.8. Risks relating to financial instruments**

Market risks in respect of non-current financial assets, cash equivalents, derivative instruments and debt are described in the risk factors presented in Item 3.D. and Item 11.

Credit risk is the risk that customers may fail to pay their debts. This risk also arises as a result of the concentration of the Group's sales with its largest customers, in particular certain wholesalers in the United States. Customer credit risk is described in the risk factors presented in Item 3.D.

**B.9. Inventories**

Inventories are measured at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

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The cost of finished goods inventories includes costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

### **B.10. Cash and cash equivalents**

Cash and cash equivalents as shown in the consolidated balance sheet and statement of cash flows comprise cash, plus liquid short-term investments that are (i) readily convertible into cash, and (ii) subject to an insignificant risk of changes in value in the event of movements in interest rates.

### **B.11. Treasury shares**

In accordance with IAS 32, Sanofi treasury shares are deducted from equity, irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale, impairment or cancellation of treasury shares.

### **B.12. Provisions for risks**

In accordance with IAS 37 (Provisions, Contingent Liabilities and Contingent Assets), Sanofi records a provision where it has a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

If the obligation is expected to be settled more than twelve months after the balance sheet date, or has no definite settlement date, the provision is recorded under *Provisions and other non-current liabilities*.

Provisions relating to the insurance programs, in which the Group's captive insurance company participates, are based on risk exposure estimates calculated by management, with assistance from independent actuaries, using IBNR (Incurred But Not Reported) techniques. These techniques use past claims experience, within the Group and in the market, to estimate future trends in the cost of claims.

Contingent liabilities are not recognized, but are disclosed in the notes to the financial statements unless the possibility of an outflow of economic resources is remote.

Provisions are estimated on the basis of events and circumstances related to present obligations at the balance sheet date, of past experience, and to the best of management's knowledge at the date of preparation of the financial statements.

Reimbursements offsetting the probable outflow of resources are recognized as assets only if it is virtually certain that they will be received. Contingent assets are not recognized.

Restructuring provisions are recognized if the Group has a detailed, formal restructuring plan at the balance sheet date and has announced its intention to implement this plan to those affected by it.

No provisions are recorded for future operating losses.

Sanofi records non-current provisions for certain obligations such as legal environmental obligations and litigation where an outflow of resources is probable and the amount of the outflow can be reliably estimated. Where the effect of the time value of money is material, these provisions are measured at the present value of the expenditures expected to be required to settle the obligation, calculated using a discount rate that reflects an estimate of the time value of money and the risks specific to the obligation.

Increases in provisions to reflect the effects of the passage of time are recognized in *Financial expenses*.

**B.13. Emission rights**

Under international agreements, the European Union has committed to reducing greenhouse gas emissions and instituted an emissions allowance trading scheme. Approximately ten Sanofi sites in Europe are covered by the scheme. Sanofi accounts for emission allowances as follows: the annual allowances allocated by government are recognized as intangible assets measured at fair value at the date of initial recognition, with a matching liability recognized to reflect the government grant effectively arising from the fact that allowances are issued free of charge. As and when allowances are consumed, they are transferred to Deliverable allowances in order to recognize the liability to government in respect of actual CO<sub>2</sub> emissions. If the allocated allowances are insufficient to cover actual emissions, an expense is recognized in order to reflect the additional allowances deliverable; this expense is measured at the market value of the allowances.

#### **B.14. Revenue recognition**

Revenue arising from the sale of goods is presented in the income statement under *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities.

Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group, in accordance with IAS 18 (Revenue). In particular, the contracts between Sanofi Pasteur and government agencies specify terms for the supply and acceptance of batches of vaccine; revenue is recognized when these conditions are met.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Group offers various types of price reductions on its products. In particular, products sold in the United States are covered by various governmental programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Returns, discounts, incentives and rebates, as described above, are recognized in the period in which the underlying sales are recognized as a reduction of sales revenue.

These amounts are calculated as follows:

Provisions for chargeback incentives are estimated on the basis of the relevant subsidiary's standard sales terms and conditions, and in certain cases on the basis of specific contractual arrangements with the customer. They represent management's best estimate of the ultimate amount of chargeback incentives that will eventually be claimed by the customer.

Provisions for rebates based on attainment of sales targets are estimated and accrued as each of the underlying sales transactions is recognized.

Provisions for price reductions under Government and State programs, largely in the United States, are estimated on the basis of the specific terms of the relevant regulations and/or agreements, and accrued as each of the underlying sales transactions is recognized.

Provisions for sales returns are calculated on the basis of management's best estimate of the amount of product that will ultimately be returned by customers. In countries where product returns are possible, Sanofi has implemented a returns policy that allows the customer to return products within a certain period either side of the expiry date (usually 6 months before and 12 months after the expiry date). The provision is estimated on the basis of past experience of sales returns.

The Group also takes account of factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products, the entry of competing generics into the market, and the launch of over-the-counter medicines.

In each case, the provisions are subject to continuous review and adjustment as appropriate based on the most recent information available to management.

The Group believes that it has the ability to measure each of the above provisions reliably, using the following factors in developing its estimates:

the nature and patient profile of the underlying product;



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the applicable regulations and/or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;

historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;

past experience and sales growth trends for the same or similar products;

actual inventory levels in distribution channels, monitored by the Group using internal sales data and externally provided data;

the shelf life of the Group's products; and

market trends including competition, pricing and demand.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group (see Note C.), are presented in *Other revenues*.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**B.15. Cost of sales**

Cost of sales consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment and software, personnel costs, and other expenses attributable to production.

**B.16. Research and development expenses**

Internally generated research costs are expensed as incurred.

Internally generated pharmaceutical development costs are also expensed as incurred; they are not capitalized, because the criteria for capitalization are considered not to have been met until marketing approval for the related product has been obtained from the regulatory authorities. Recharges to or contributions from alliance partners are recorded as a reduction in **Research and development expenses**.

Note B.4.1. Research and development not acquired in a business combination and Note B.4.3. Intangible assets acquired in a business combination describe the principles applied to the recognition of separately acquired research and development.

**B.17. Other operating income and expenses**

**B. 17.1. Other operating income**

**Other operating income** includes the share of profits that Sanofi is entitled to receive from alliance partners in respect of product marketing agreements. It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion agreements.

Upfront payments received are deferred for as long as a service obligation remains. Milestone payments are assessed on a case by case basis, and recognized in the income statement on delivery of the products and/or provision of the services in question. Revenue generated in connection with these services is recognized on the basis of delivery of the goods or provision of the services to the other contracting party.

This line also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.4.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

**B.17.2. Other operating expenses**

*Other operating expenses* mainly comprise the share of profits that alliance partners are entitled to receive from Sanofi under product marketing agreements.

**B.18. Amortization and impairment of intangible assets**

**B.18.1. Amortization of intangible assets**

The expenses recorded in this line item mainly comprise amortization of product rights (see Note D.4.), which are presented as a separate item because the benefit of these rights to the Group's commercial, industrial and development functions cannot be separately identified.

Amortization of software is recognized as an expense in the income statement, in the relevant line items of expense by function.

**B.18.2. Impairment of intangible assets**

This line item records impairment losses (other than those associated with restructuring) recognized against intangible assets (including goodwill), and any reversals of such impairment losses.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****B.19. Fair value remeasurement of contingent consideration liabilities**

Changes in the fair value of contingent consideration in the books of the acquired entity or recognized in a business combination and initially recognized as a liability are reported in profit or loss in accordance with the principles described in Note B.3.1. Such adjustments are reported separately in the income statements, in the line item *Fair value remeasurement of contingent consideration liabilities*. This line item also includes the effect of the unwinding of discount and of exchange rate movements where the liability is expressed in a currency other than the functional currency of the reporting entity.

**B.20. Restructuring costs and other gains and losses, and litigation****B.20.1. Restructuring costs**

*Restructuring costs* include early retirement benefits, compensation for early termination of contracts, and rationalization costs relating to restructured sites. Asset impairment losses directly attributable to restructuring are also recorded on this line. Restructuring costs included on this line relate only to unusual and major restructuring plans.

**B.20.2. Other gains and losses, and litigation**

This line item includes the impact of material transactions of an unusual nature or amount and which the Group believes it necessary to report separately in the income statement in order to improve the relevance of the financial statements.

The line item *Other gains and losses, and litigation* includes the following:

gains and losses on major disposals of property, plant and equipment, of intangible assets, of assets (or groups of assets and liabilities) held for sale, or of a business within the meaning of the revised IFRS 3, not considered as restructuring costs;

Impairment losses and reversals of impairment losses on assets (or groups of assets and liabilities) held for sale, not considered as restructuring costs;

expenses related to the reclassification of non-current assets previously accounted for as held-for-sale, where the amounts involved relate to previously-reported periods;

gains on bargain purchases; and

costs and provisions relating to major litigation.

**B.21. Financial expenses/income**

**B.21.1. Financial expenses**

*Financial expenses* mainly comprise interest charges on debt financing, negative changes in the fair value of financial instruments (where changes in fair value are taken to the income statement), realized and unrealized foreign exchange losses on financing and investing activities, and impairment losses on financial instruments. They also include any reversals of impairment losses on financial instruments.

*Financial expenses* also include the expenses arising from the unwinding of discount on non-current provisions, except provisions for retirement benefits and other long-term employee benefits. This line does not include cash discounts, which are deducted from net sales.

**B.21.2. Financial income**

*Financial income* includes interest and dividend income, positive changes in the fair value of financial instruments (where changes in fair value are taken to the income statement), realized and unrealized foreign exchange gains on financing and investing activities, and gains or losses on disposals of financial assets.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**B.22. Income tax expense**

*Income tax expense* includes all current and deferred taxes of consolidated companies.

Sanofi Group accounts for deferred taxes in accordance with IAS 12 (Income Taxes), using the methods described below.

Deferred tax assets and liabilities are recognized on taxable and deductible temporary differences, and tax loss carry-forwards. Temporary differences are differences between the carrying amount of an asset or liability in the balance sheet and its tax base.

Reforms to French business taxes were enacted on December 31, 2009 and apply as from January 1, 2010. The new tax, the CET (*Contribution Economique Territoriale*), has two components: the CFE (*Cotisation Fonciere des Entreprises*) and the CVAE (*Cotisation sur la Valeur Ajoutée des Entreprises*). The second component is determined by applying a rate to the amount of value added generated by the business during the year.

Given that part of the CVAE component is calculated as the amount by which certain revenues exceed certain expenses, and given that this tax will be borne primarily by companies that own intellectual property rights, on income derived from those rights (royalties, and margin on sales to third parties and to other Group companies), the Group regards the CVAE component as meeting the definition of income taxes specified in IAS 12, paragraph 2 ( taxes which are based on taxable profits ).

Deferred tax assets and liabilities are calculated using the tax rate expected to apply in the period when a temporary difference is expected to reverse, based on tax rates enacted or substantively enacted at the balance sheet date.

Unused tax losses and unused tax credits are recognized as deferred tax assets to the extent that it is probable that future taxable profits will be available against which they can be utilized.

Sanofi Group recognizes a deferred tax liability for temporary differences relating to interests in subsidiaries, associates and joint ventures except when the Group is able to control the timing of the reversal of the temporary differences. This applies in particular when the Group is able to control dividend policy and it is probable that the temporary differences will not reverse in the foreseeable future.

No deferred tax is recognized on eliminations of intragroup transfers of interests in subsidiaries, associates or joint ventures.

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For consolidation purposes, each tax entity calculates its own net deferred tax position. All net deferred tax asset and liability positions are then aggregated and shown as separate line items on the assets and liabilities sides of the consolidated balance sheet respectively. Deferred tax assets and liabilities can be offset only if (i) the Group has a legally enforceable right to set off current tax assets and current tax liabilities, and (ii) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority.

Deferred taxes are not discounted, except implicitly in the case of deferred taxes on assets and liabilities which are themselves discounted.

Withholding taxes on intragroup royalties and dividends, and on royalties and dividends collected from third parties, are accounted for as current income taxes.

In accounting for business combinations, the Sanofi Group complies with the revised IFRS 3 as regards the recognition of deferred tax assets after the initial accounting period. This means that the Group recognizes in profit or loss for the period any deferred tax assets recognized by the acquiree after the end of this period on temporary differences or tax loss carry-forwards existing at the acquisition date. Under the pre-revision IFRS 3, applicable prior to January 1, 2010, such items were recognized as a reduction in the amount of goodwill.

*Income tax expense* includes the effect of tax disputes, and any penalties and late payment interest arising from such disputes.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**B.23. Employee benefit obligations**

Sanofi Group offers retirement benefits to employees and retirees of the Group. These benefits are accounted for in accordance with IAS 19 (Employee Benefits).

These benefits are in the form of either defined-contribution plans or defined-benefit plans.

In the case of defined-contribution plans, the contributions paid by Sanofi are expensed in the period in which they occur, and no actuarial estimate is performed.

In the case of defined-benefit plans, Sanofi recognizes its obligations to employees as a liability, based on an actuarial estimate of the rights vested and/or currently vesting in employees and retirees using the projected unit credit method. The amount of the liability is recognized net of the fair value of plan assets.

These estimates are performed at least once a year, and rely on demographic and financial assumptions such as life expectancy, employee turnover, and salary increases. The estimated obligation is discounted.

In the case of multi-employer defined-benefit plans where plan assets cannot be allocated to each participating employer with sufficient reliability, the plan is accounted for as a defined-contribution plan, in accordance with paragraph 30 of IAS 19.

Obligations in respect of other post-employment benefits (healthcare, life insurance) offered by Group companies to employees are also recognized as a liability based on an actuarial estimate of the rights vested or currently vesting in employees and retirees at the balance sheet date.

Actuarial gains and losses relating to defined-benefit plans (pensions and other post-employment benefits), arising from the effects of changes in actuarial assumptions and experience adjustments, are recognized in equity net of deferred taxes via the consolidated statement of comprehensive income, under the option allowed by the amendment to IAS 19. All unrecognized actuarial gains and losses at the transition date, January 1, 2004, were recognized in *Equity attributable to equity holders of Sanofi* at that date in accordance with the optional treatment allowed in IFRS 1.

Past service cost is recognized as an expense on a straight-line basis over the average period until the benefits become vested. If benefits are already vested on the introduction of, or changes to, a defined-benefit plan, past service cost is recognized immediately as an expense.



Actuarial gains and losses and past service cost relating to other long-term employee benefits are recognized immediately in the income statement.

## **B.24. Share-based payment**

### **B.24.1. Stock option plans**

Sanofi has granted a number of equity-settled, share-based payment plans (stock option plans) to some of its employees.

In accordance with IFRS 2 (Share-Based Payment), services received from employees as consideration for stock options are recognized as an expense in the income statement, with the matching entry recognized in equity. The expense corresponds to the fair value of the stock option plans, and is charged to income on a straight-line basis over the four-year vesting period of the plan.

The fair value of stock option plans is measured at the date of grant using the Black-Scholes valuation model, taking into account the expected life of the options. The expense recognized in this evaluation takes into account the expected cancellation rate of the options. The expense is adjusted over the vesting period to reflect the actual cancellation rates resulting from the departure of the holders of the options.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**B.24.2. Employee share ownership plans**

The Sanofi Group may offer its employees the opportunity to subscribe to reserved share issues at a discount to the reference market price. Shares allotted to employees under these plans fall within the scope of IFRS 2. The discount is measured at the subscription date and recognized as an expense, with no reduction for any lock-up period.

**B.24.3. Restricted share plans**

Sanofi may award restricted share plans to certain of its employees. The terms of these plans may make the award contingent on performance criteria for some grantees.

In accordance with IFRS 2, an expense equivalent to the fair value of such plans is recognized on a straight line basis over the vesting period of the plan, with the matching entry credited to equity. Depending on the country, the vesting period of such plans is either two or four years. Plans with a two-year vesting period are subject to a two-year lock-up period.

The fair value of stock option plans is based on the fair value of the equity instruments granted, representing the fair value of the services received during the vesting period. The fair value of an equity instrument granted under a plan is the market price of the share at the grant date, adjusted for expected dividends during the vesting period.

**B.25. Earnings per share**

Basic earnings per share is calculated using the weighted average number of shares outstanding during the reporting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of Sanofi shares held by the Group. Diluted earnings per share is calculated on the basis of the weighted average number of ordinary shares, computed using the treasury stock method.

This method assumes that (a) all outstanding dilutive options and warrants are exercised, and (b) the Group acquires its own shares at the quoted market price for an amount equivalent to the cash received as consideration for the exercise of the options or warrants, plus the expense arising on unamortized stock options.

In the event of a stock split or restricted share issue, earnings per share for prior periods is adjusted accordingly.

**B.26. Segment information**

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the Group's chief operating decision maker. The performance of these segments is monitored individually using internal reports and common indicators.

The Group is comprised of three operating segments: Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health. All other activities are combined in a separate segment, Other. These segments reflect the Group's internal organizational structure, and are used internally for performance measurement and resource allocation.

Information on operating segments is provided in Note D.34. Split of net sales and Note D.35. Segment information .

**B.27. Management of capital**

In order to maintain or adjust the capital structure, the Group can adjust the amount of dividends paid to shareholders, or repurchase its own shares, or issue new shares, or issue securities giving access to its capital.

The following objectives are defined under the terms of the Group's share repurchase programs:

the implementation of any stock option plan giving entitlement to purchase shares in the Sanofi parent company;

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the allotment or sale of shares to employees under statutory profit-sharing schemes and employee savings plans;

the award of restricted shares;

the cancellation of some or all of the repurchased shares;

market-making in the secondary market in the shares by an investment services provider under a liquidity contract in compliance with the ethical code recognized by the *Autorité des marchés financiers*;

the delivery of shares on the exercise of rights attached to securities giving access to the capital by redemption, conversion, exchange, presentation of a warrant or any other means;

the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers and acquisitions;

the execution by an investment services provider of purchases, sales or transfers by any means, in particular via off-market trading;

or any other purpose that is or may in the future be authorized under the applicable laws and regulations.

The Group is not subject to any constraints on equity capital imposed by third parties.

The gearing ratio (the ratio of debt, net of cash and cash equivalents to total equity) is a non-GAAP financial indicator used by management to measure overall net indebtedness and to manage the Group's equity capital.

Total equity includes *Equity attributable to equity holders of Sanofi* and *Equity attributable to non-controlling interests*, as shown on the consolidated balance sheet. Debt, net of cash and cash equivalents is defined as short-term debt plus long-term debt, plus related interest rate and currency derivatives used to hedge debt, minus cash and cash equivalents.

For trends in this ratio, see Note D.17.

**B.28. New IFRS standards, amendments and interpretations applicable from 2012 onwards**

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New standards, amendments and interpretations applicable in 2011 with an impact on the consolidated financial statements are described in Note A.2. New standards, amendments and interpretations applicable in 2011 .

The note below describes standards, amendments and interpretations issued by the IASB that will be mandatorily applicable in 2012 or subsequent years, and the Group's position regarding future application. None of these standards, amendments or interpretations has been early adopted by the Group.

### **B.28.1. Standards and amendments applicable to the Sanofi consolidated financial statements**

In May 2011, the IASB issued five pronouncements designed to improve the principles applied in the preparation of consolidated financial statements and the disclosure requirements for joint arrangements and for any type of entity in which an interest is held. None of these pronouncements have yet been endorsed by the European Union:

IFRS 10, Consolidated Financial Statements, supersedes the parts of IAS 27, Consolidated and Separate Financial Statements, relative to consolidated financial statements and SIC-12, Consolidation – Special Purpose Entities. This standard redefines the concept of control. Its impact, in particular as regards the scope of consolidation of the Group is currently under review. The Group does not expect the financial statements to be materially affected by it.

IFRS 11, Joint Arrangements, replaces IAS 31, Interests in Joint Ventures and SIC-13, Jointly Controlled Entities – Non-Monetary Contributions by Venturers. This standard establishes principles that are applicable to the accounting for arrangements that give joint control over a business, which are

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

classified either as a joint operation or as a joint venture. Whether an arrangement is classified as a joint operation or a joint venture depends on the rights related to the assets and the obligations related to the liabilities of each of the parties under the contractual arrangement establishing joint control. Under IFRS 11, proportionate consolidation is no longer a permitted option. The option to use proportionate consolidation has not been used by the Group. The impact of this standard is currently under review; the Group does not expect it to materially alter the financial statements.

IFRS 12, Disclosures of Interests in Other Entities covers all the disclosures to be made when an entity holds interests in subsidiaries, associates or unconsolidated structured entities, regardless of the level of control or influence over the entity. The impact of this standard on the notes to the financial statements is currently under review.

Two standards IAS 27, Consolidated and Separated Financial Statements, and IAS 28, Investments in Associates, were amended, to bring them into line with the changes introduced by the publication of IFRS 10, IFRS 11 and IFRS 12.

The amended IAS 27, Separate Financial Statements, will now refer solely to the provisions applicable to the recognition of interests in subsidiaries, jointly controlled entities and associates for reporting entities that prepare separate financial statements in accordance with IFRS.

The amended IAS 28, Investments in Associates and Joint Ventures must be applied to recognize interests in associates and joint ventures, as defined in IFRS 11.

These new pronouncements will be applicable from January 1, 2013.

In May 2011, the IASB and the FASB jointly issued a standard proposing a common definition of fair value, and application guidance. The standard IFRS 13, Fair Value Measurement, under IFRS also specifies the disclosures to be made to help users of financial statements understand how fair value is measured. The standard does not change the scope of application of fair value accounting. It will have mandatory application as from January 1, 2013 and has not yet been endorsed by the European Union.

In June 2011, the IASB issued the amended IAS 19. The standard will have mandatory application as from January 1, 2013 and has not yet been endorsed by the European Union. The amendment makes the main following changes to the standard:

It changes primarily the methods used to determine the assumption regarding the long-term return on plan assets, which will be based on the discount rate used to measure the present value of the obligation. The method currently used is based on the expected return on plan assets. The application of this change would have had a negative impact on income before tax of approximately 68 million euros for the 2011 fiscal year.

It eliminates the option of deferring actuarial gains and losses under the corridor method. The new standard makes it mandatory to recognize all actuarial gains and losses directly in equity. The Group already applies this method.

It eliminates the deferral of past service cost on unvested benefits: such costs will be recognized immediately in profit or loss.

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In December 2011, the IASB issued two amendments relative to the offsetting of financial assets and financial liabilities:

Amendment to IFRS 7, Financial Instruments: Disclosures, applicable retrospectively to fiscal years starting on or after January 1, 2013, which enhances the requirements for disclosures to be made in the notes to the financial statements in the event of offsetting of financial assets and financial liabilities;

Amendment to IAS 32, Financial Instruments: Presentation, applicable retrospectively to annual periods beginning on or after January 1, 2014, which clarifies the rules of offsetting.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

These amendments have no impact on the Group's financial statements.

The IASB issued two amendments in 2010:

Amendment to IFRS 7, Financial Instruments: Disclosures. This amendment is applicable to annual periods beginning on or after July 1, 2011, and has been endorsed by the European Union. It is intended to improve disclosure about transfers of financial assets, in particular securitization transactions. It does not alter the way in which securitizations are currently accounted for, but specifies the disclosures that must be made.

Amendment to IAS 12, Income Taxes, titled Recovery of underlying assets. This amendment, applicable to fiscal years beginning on or after January 1, 2012, and which has not yet been endorsed by the European Union, provides a practical approach for measuring deferred tax liabilities and deferred tax assets when investment property is measured using the fair value model in IAS 40, Investment Property. Because the Group does not own any investment property measured in accordance with IAS 40, this amendment does not apply to the consolidated financial statements.

In late 2009, the IASB issued IFRS 9, Financial Instruments, which has not yet been endorsed by the European Union: This standard is applicable to annual periods beginning on or after January 1, 2015, and completes the first of the three phases of the IASB financial instruments project. The next two phases will deal with Financial Instruments: Amortized Cost and Impairment and Hedge Accounting. The three phases of IFRS 9 are intended to replace IAS 39, Financial Instruments: Recognition and Measurement. The Group will assess the overall impact of IFRS 9 once all the phases have been published.

**B.28.2. New interpretations**

The IASB has also issued IFRIC 20, Stripping Costs in the Production Phase of a Surface Mine. This interpretation will be applicable from January 2013 onwards and has not yet been endorsed by the European Union. It does not apply to the activities of the Group.

**C. ALLIANCES**

**C.1. Alliance arrangements with Bristol-Myers Squibb (BMS)**

Two of the Group's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).



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As inventor of the two molecules, Sanofi is paid a royalty on a portion of sales generated by these products (i.e. in the countries of co-promotion and co-marketing). The portion of this royalty received by Sanofi on sales generated by BMS in territories under the operational management of BMS (see below) is recorded in *Other revenues*. As co-developers of the products, Sanofi and BMS each receive equal development royalties from their two licensees, which have been responsible, since 1997, for marketing the products using their local distribution networks, composed of subsidiaries of both groups. These licensees operate in two separate territories: (i) Europe, Africa, Asia and the Middle East, under the operational management of Sanofi; and (ii) other countries (excluding Japan), under the operational management of BMS. In Japan, since June 2008 Aprovel<sup>®</sup> has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd. The alliance with BMS does not cover the rights to Plavix<sup>®</sup> in Japan, where the product is marketed by Sanofi.

The products are marketed in different ways in different countries.

Co-promotion consists of a pooling of sales resources under a single brand name, and is preferably achieved through contracts or through appropriate tax-transparent legal entities. Each partner records directly its share of taxable income.

Co-marketing consists of separate marketing of the products by each local affiliate using its own name and resources under different brand names for the product.

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In certain countries of Eastern Europe, Africa, Asia, Latin America and the Middle East, the products are marketed on an exclusive basis by Sanofi.

In the territory managed by Sanofi, operations are recognized by the Group as follows:

- (i) In most countries of Western Europe and in some Asian countries (excluding Japan) for clopidogrel bisulfate (Plavix®/Iscover®) only, co-promotion is used for both products. The legal entities used are partnerships (*sociétés en participation*) or other tax-transparent entities, which are majority-owned by and under the operational management of the Group. Sanofi recognizes all the revenue associated with the sale of the drugs, as well as the corresponding expenses. The share of profits reverting to BMS subsidiaries is shown in *Net income attributable to non-controlling interests* in the income statement, with no tax effect (because BMS receives a pre-tax share of profits).

The line item *Non-controlling interests, excluding BMS* in the consolidated statement of cash flows takes account of the specific terms of the alliance agreement.

- (ii) In Germany, Spain and Greece, and in Italy for irbesartan (Aprovel®/Avapro®/ Karvea®/Karvezide®) only, co-marketing is used for both products, and Sanofi recognizes revenues and expenses generated by its own operations.
- (iii) In those countries in Eastern Europe, Africa, the Middle East and Asia (excluding Japan) where the products are marketed exclusively by Sanofi, the Group recognizes revenues and expenses generated by its own operations. Sanofi has had the exclusive right to market Aprovel® in Scandinavia and in Ireland since September 2006, and the exclusive right to market Plavix® in Malaysia since January 1, 2010.

In the territory managed by BMS, operations are recognized by the Group as follows:

- (i) Co-promotion is used in the United States, Canada and Puerto Rico through entities that are majority-owned by and under the operational management of BMS. Sanofi does not recognize revenues; rather, it invoices the entity for its promotion expenses, records its royalty income in *Other revenues*, and records its share of profits (net of tax) in *Share of profit/loss of associates and joint ventures*.
- (ii) In Brazil, Mexico, Argentina and Australia for clopidogrel bisulfate (Plavix®/Iscover®) and for irbesartan (Aprovel®/Avapro®/Karvea®/Karvezide®) and in Colombia for clopidogrel bisulfate only, co-marketing is used, and Sanofi recognizes revenues and expenses generated by its own operations.
- (iii) In certain other Latin American countries, where the products are marketed exclusively by Sanofi, the Group recognizes revenues and expenses generated by its own operations.

**C.2. Alliance agreements with Warner Chilcott (previously with Procter & Gamble Pharmaceuticals, the Alliance Partner )**

Actonel® (risedronate sodium) is a new-generation bisphosphonate indicated for the treatment and prevention of osteoporosis. Historically, Actonel® was developed and marketed in collaboration with Procter & Gamble Pharmaceuticals. Procter & Gamble sold its pharmaceutical interests to Warner Chilcott on October 30, 2009. Consequently, Actonel® has, since that date, been marketed in collaboration with Warner Chilcott.

This alliance agreement covers the worldwide development and marketing of the product, except for Japan for which the Group holds no rights.

Local marketing arrangements may take various forms:

Co-promotion, whereby sales resources are pooled but only one of the two parties to the alliance agreement (Sanofi or the Alliance Partner) invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. The Alliance Partner sells the product and incurs all the related costs in France and Canada. This co-promotion scheme also included Germany, Belgium and Luxembourg until December 31, 2007, the Netherlands until March 31, 2008,

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and the United States and Puerto Rico until March 31, 2010. Sanofi recognizes its share of revenues under the agreement as a component of operating income on the *Other operating income* line. Since April 1, 2010, Sanofi has received royalties from the Alliance Partner on sales made by the Alliance Partner in the United States and Puerto Rico. In the secondary co-promotion territories (the United Kingdom until December 31, 2008, Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia) Sanofi sells the product, and recognizes all the revenues from sales of the product along with the corresponding expenses. The share due to the Alliance Partner is recognized in *Cost of sales*.

Co-marketing, which applies in Italy, whereby each party to the alliance agreement sells the product in the country under its own name, and recognizes all revenue and expenses from its own operations in its income statement. Each company also markets the product independently under its own brand name in Spain, although Spain is not included in the co-marketing territory.

The product has been marketed by the Alliance Partner independently in Germany, Belgium and Luxembourg since January 1, 2008; in the Netherlands since April 1, 2008; and in the United Kingdom since January 1, 2009. Sanofi recognizes its share of revenues under the alliance agreement in *Other operating income*.

In all other territories, Sanofi has exclusive rights to sell the product and recognizes all revenue and expenses from its own operations in its income statement, but in return for these exclusive rights pays the Alliance Partner a royalty based on actual sales. This royalty is recognized in *Cost of sales*.

In 2010, Sanofi and Warner Chilcott had begun negotiations on the future of their alliance arrangements. In an arbitration proceeding, an arbitration panel decided on July 14, 2011 that the termination by Warner Chilcott of an ancillary agreement did not entail the termination of the Actonel® Alliance. Pursuant to this decision, the alliance will remain in effect until January 1, 2015.

***D. PRESENTATION OF THE FINANCIAL STATEMENTS*****D.1. Impact of changes in the scope of consolidation**

Business combinations, completed on or after January 1, 2010, are accounted for using the acquisition method in accordance with the revised IFRS 3. The accounting policies applicable to business combinations are described in Note B.3.1.

**D.1.1. Genzyme acquisition**

Sanofi acquired Genzyme Corporation (Genzyme) at a cash price of \$74 per share or \$20.4 billion ( 14.3 billion) on April 4, 2011, the completion date of the public exchange offer for all of the outstanding shares of common stock of Genzyme. Genzyme, a wholly-owned subsidiary of Sanofi, is a biotechnology group headquartered in Cambridge, Massachusetts (United States), whose shares were previously listed on the NASDAQ market. Genzyme's primary areas of focus are rare diseases, renal-endocrinology, oncology and biosurgery. In 2010, Genzyme generated net sales of approximately \$4 billion. The group employs nearly 10,000 people and has operations in approximately 70 locations. With this acquisition, Sanofi will expand its reach in biotechnologies and intends to make Genzyme its global center of excellence in rare diseases.

As part of the acquisition, Sanofi issued one contingent value right (CVR) per Genzyme share held to Genzyme shareholders. Sanofi issued 291 million CVRs.

The CVRs (representing a maximum commitment of \$4.1 billion at the acquisition date) are listed on the NASDAQ market under the ticker GCVRZ and have been quoted since April 4, 2011. As of that date, the quoted price per CVR was \$2.35 per share totaling \$685 million ( 481 million) for all the shares issued. This price was used as the basis for determining the overall fair value of the contingent consideration. In accordance with revised IFRS 3, this contingent consideration is measured at fair value at the acquisition date and included in the price paid to acquire Genzyme for the purposes of determining goodwill. The liability related to this contingent consideration is recognized in the balance sheet line item *Liabilities related to business combinations and to non-controlling interests* (see Note D.18.).

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Under the terms of the CVR agreement, each CVR entitles the holder to additional cash payments, if certain milestones are met over specified period relating to Lemtrada (the registered name submitted to health authorities for the investigational agent alemtuzumab), or if specified production levels of Cerezyme® and Fabrazyme® are met in 2011. The CVRs will expire on the earlier of December 31, 2020, or the attainment of the fourth sales milestone of Lemtrada. Each milestone and payment may occur once only. The milestones and payments per CVR are summarized below:

\$1 if certain production levels of Cerezyme®/Fabrazyme® are met during 2011;

\$1 if final approval by the U.S. Food and Drug Administration of Lemtrada for the treatment of multiple sclerosis is obtained no later than March 31, 2014;

\$2 if post-launch net sales of Lemtrada is \$400 million or more over specified periods and in specified territories;

\$3 if such net sales reach at least \$1.8 billion worldwide over a period of four consecutive calendar quarters;

\$4 if such net sales reach at least \$2.3 billion worldwide over a period of four consecutive calendar quarters;

\$3 if such net sales reach at least \$2.8 billion worldwide over a period of four consecutive calendar quarters.

At December 31, 2011, the maximum commitment totaled \$3.8 billion, as the Cerezyme®/Fabrazyme® production levels were not reached in 2011.

The provisional purchase price allocation is as follows:

<i>( million)</i>	<b>Fair value at acquisition date</b>
Property, plant and equipment	1,933
Other intangible assets	10,063
Non-current financial assets	102
Inventories	925
Accounts receivable	764
Cash and cash equivalents	1,267
Long-term and short-term debt	(835)
Liability related to the Bayer contingent consideration	(585)
Accounts payable	(313)
Deferred taxes	(2,422)
Other assets and liabilities	(171)
<b>Net assets of Genzyme as of April 4, 2011</b>	<b>10,728</b>
<b>Goodwill</b>	<b>4,086</b>
<b>Purchase price <sup>(1)</sup></b>	<b>14,814</b>

*(1) Includes the CVRs valuation as of the acquisition date for the amount of 481 million.*

Prior to Sanofi's acquisition of Genzyme, in May 2009, Genzyme acquired the worldwide development and marketing rights to alemtuzumab (under the brand name Lemtrada™), a molecule currently under development for multiple sclerosis, as well as, the rights to the products Campath®, Fludara® and Leukine® from Bayer Schering Pharma A.G. (Bayer). As part of this agreement, Bayer is entitled to receive the following contingent payments:

a percentage of alemtuzumab sales, up to a maximum of \$1,250 million or over a maximum period of ten years, whichever is achieved first;

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a percentage of aggregate sales of Campath<sup>®</sup>, Fludara<sup>®</sup> and Leukine<sup>®</sup> up to a maximum of \$500 million (of which \$230 million were paid as of the acquisition date) or over a maximum period of eight years, whichever is achieved first;

milestone payments up to \$150 million based on the aggregate sales of Campath<sup>®</sup>, Fludara<sup>®</sup> and Leukine<sup>®</sup> for years 2011 to 2013;

milestone payments based on specified levels of worldwide sales of alemtuzumab beginning in 2021 provided Genzyme does not exercise its right to buy out these milestone payments by making a one-time payment not exceeding \$900 million.

This pre-existing additional contingent purchase consideration is measured at its fair value as of April 4, 2011, and is recognized as a liability in the balance sheet line item ***Liabilities related to business combinations and to non-controlling interests***. The amount is remeasured at fair value at each reporting date. The impact of the resulting fair value adjustment is recognized in profit or loss in the line item ***Fair value remeasurement of contingent consideration liabilities***, similarly to other contingent consideration on business combinations (see Note D.18.).

The goodwill arising from Sanofi's acquisition of Genzyme mainly represents the portfolio of future products in the upstream research and development phase not separately identified at the acquisition date; the capacity to renew the existing product portfolio based on specialized organizational structures; the scientific expertise of Genzyme staff; as well as, the advantages gained from creating new growth platforms; expected future synergies; and the other beneficial effects of combining Genzyme with Sanofi. This goodwill does not give rise to any deduction for tax purposes.

The goodwill was determined on the basis of the provisional fair values of the assets and liabilities identified at the time of the acquisition; it will be adjusted, within a period of no more than twelve months from the acquisition date, if these fair values change as a result of circumstances existing at the acquisition date. These fair value adjustments may arise in respect of property, plant and equipment, intangible assets and inventories, upon completion of the necessary valuations, and physical verifications of such assets. The amount of provisions may also be adjusted as a result of ongoing procedures to identify and measure liabilities and contingent liabilities, including tax, environmental risks, and litigation. The amount of deferred taxes may also be adjusted during the purchase price allocation period.

Since the acquisition date, Genzyme has generated net sales of 2,395 million and business operating income of 593 million (see definition in Note D.35. Segment Information). Over the same period, Genzyme made a negative contribution of 749 million to consolidated net income (after taking account of expenses during the period associated with the remeasurement of assets at fair value on recognition at the acquisition date). Over the twelve months of the year ended December 31, 2011, Genzyme net sales amounted to 3,133 million.

The acquisition costs recognized in the period amounted to 65 million, mostly recorded in the line item ***Other operating expenses***.

The impact of this acquisition as reflected in the statements of cash flows in the line item ***Acquisitions of investments in consolidated entities, net of cash acquired***, is a net cash outflow of 13.1 billion.

**D.1.2. Other business combinations during 2011**



The other acquisitions in 2011 were as follows:

**- BMP Sunstone**

On February 24, 2011, Sanofi completed the acquisition of 100% of BMP Sunstone Corporation, a pharmaceutical company previously quoted on the NASDAQ market, which is developing a portfolio of branded pharmaceuticals and healthcare products in China. Through BMP Sunstone, the Group manufactures pediatric and feminine healthcare products, sold in pharmacies across the country.

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The provisional purchase price allocation is shown in the table below:

( million)	Fair value at acquisition date
Property, plant and equipment	17
Other intangible assets	199
Inventories	5
Other assets and liabilities	(42)
Deferred taxes	(129)
<b>Net assets of BMP Sunstone as of February 24, 2011</b>	<b>50</b>
<b>Goodwill</b>	<b>334</b>
<b>Purchase price</b>	<b>384</b>

Since acquisition date, the net sales and business operating income (see definition in Note D.35. Segment Information ) of the BMP Sunstone entities amounted to 47 million and 0.1 million respectively. The contribution of the BMP Sunstone entities to consolidated net income was (24) million (amount including the expenses for the period related to the remeasurement of assets at fair value at the acquisition date).

The residual goodwill primarily reflects the advantages from the creation of a new Consumer Health Care growth platform in China, which supports the launch of new product extensions for current brands and access to certain markets in China and by expected future synergies related to the combination of Sanofi and BMP Sunstone. This amount does not result in a tax deduction.

The acquisition costs recorded in income during the period totaled 4 million, primarily recognized in the line item *Other operating expenses*.

**- Topaz Pharmaceuticals Inc.**

In October 2011, Sanofi acquired Topaz Pharmaceuticals Inc., a US pharmaceutical research company which has developed an innovative anti-parasitic treatment for head lice. An upfront payment of \$35 million was made upon closing of the transaction. The agreement provides for other potential milestone payments when the product is authorized for marketing and based on the achievement of sales targets. The total amount of the payments, including the initial payment, could reach \$207.5 million.

**- Universal Medicare**

In November 2011, Sanofi acquired the business of Universal Medicare Private Limited, one of the leading Indian producers of nutraceuticals and life management products, including vitamins, antioxidants, mineral supplements and anti-arthritis. The amount paid at acquisition was 83 million, including 13 million paid into an escrow account, which will revert to the seller based on the achievement of the objectives defined in the supply contract signed with the seller.

**D.1.3. Disposals during 2011**

On December 19, 2011, Sanofi sold the Dermik dermatology business to Valeant Pharmaceuticals International Inc. for a total of 321 million euros. The transaction includes all Dermik assets, i.e. a portfolio of several leading brands in therapeutic and esthetic dermatology like Benzaclin<sup>®</sup>, Carac<sup>®</sup> and Sculptra<sup>®</sup> and a manufacturing site in Canada.

Income before tax from this sale is recognized in the line item *Other gains and losses, and litigation* (see Note D.28.)

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**D.1.4. Business combinations during 2010**

The principal acquisitions in 2010 were as follows:

**- TargeGen, Inc. (TargeGen)**

In July 2010, Sanofi acquired 100% of the capital of TargeGen, Inc., a U.S. biopharmaceutical company developing small molecule kinase inhibitors for the treatment of certain forms of leukemia, lymphoma and other hematological malignancies and blood disorders. An upfront payment of \$75 million was made on completion. The agreement provides for other potential milestone payments at various stages in the development of TG 101348, TargeGen's principal product candidate. The total amount of payments (including the upfront payment) could reach \$560 million. The final purchase price allocation for this acquisition was not materially different from the provisional allocation.

**- Chattem, Inc. (Chattem)**

On February 9, 2010, Sanofi successfully completed a cash tender offer for Chattem, based in Chattanooga (United States). Chattem has become Sanofi's platform in the United States for consumer health products and over-the-counter products and has managed the Allegra® brand since 2011. The final purchase price allocation for this acquisition was not materially different from the provisional allocation.

The other acquisitions in 2010 were as follows:

The acquisition in April 2010 by Sanofi of a controlling interest in the capital of Bioton Vostok, a Russian insulin manufacturer. Under the terms of the agreement, put options were granted to non-controlling interests (see Note D.18.).

The formation in May 2010 of a joint venture with Nichi-Iko Pharmaceuticals Co. Ltd. (Nichi-Iko), a leading player in the Japanese generics market. As well as forming this joint venture, Sanofi also acquired a 4.66% equity interest in the capital of Nichi-Iko Pharmaceuticals Co. Ltd. (see Note D.7.).

The acquisition in June 2010 of the cosmetics and skincare products distribution activities of the Canadian company Canderm Pharma, Inc.

The acquisition in August 2010 of a 100% equity interest in the Polish company Nepentes S.A. for a consideration of PLN 425 million (€ 106 million), aimed at diversifying the Sanofi consumer health portfolio in Poland, and in Central and Eastern Europe generally.

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The acquisition in October 2010 of VaxDesign, a U.S. biotechnology company which has developed a technology for in vitro modeling of the human immune system that can be used to select the best candidate vaccines at the pre-clinical stage. Under the terms of the agreement, an upfront payment of \$55 million was made upon closing of the transaction, and a further \$5 million will be payable upon completion of a specified development milestone.

The acquisition in October 2010 of a 60% equity interest in the Chinese company Hangzhou Sanofi Minsheng Consumer Healthcare Co. Ltd, in partnership with Minsheng Pharmaceutical Co., Ltd., with Sanofi also granting the alliance partner a put option over the remaining shares not held by Sanofi (see Note D.18.).

### **D.1.5. Business combinations during 2009**

The principal acquisitions in 2009 were as follows:

#### **- BiPar**

On April 27, 2009, Sanofi acquired 100% of BiPar Sciences (BiPar), an American biopharmaceutical company developing novel tumorselective approaches for the treatment of different types of cancers. The purchase price is contingent on the achievement (regarded as probable) of milestones related to the development of BSI-201, and could reach \$500 million at the acquisition date.

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**- Medley**

On April 27, 2009, Sanofi acquired a 100% equity interest in Medley, the third largest pharmaceutical company in Brazil and a leading generics company in that country. The purchase price, based on an enterprise value of 500 million, was 348 million inclusive of acquisition-related costs.

**- Zentiva**

On March 11, 2009, Sanofi successfully closed its offer for Zentiva N.V. (Zentiva). As of December 31, 2009, Sanofi held about 99.1% of Zentiva's share capital. The purchase price was 1,200 million, including acquisition-related costs. Following the buyout of the remaining non-controlling interests, Sanofi held a 100% equity interest in Zentiva as of December 31, 2011.

Previously, Sanofi held a 24.9% interest in Zentiva, which was accounted for as an associate by the equity method (see Note D.6.).

**- Shantha Biotechnics**

In August 2009, the Group took control of Shantha Biotechnics (Shantha), a vaccines company based in Hyderabad (India), by acquiring the shares of ShanH, the owner of Shantha. In the purchase price allocation, identifiable intangible assets other than goodwill were measured at a fair value of 374 million. This amount includes the acquisition-date value of the ShanS pentavalent vaccine, which was partially written down in 2010 (see Note D.5.).

The other acquisitions during 2009 were:

Fovea Pharmaceuticals SA (Fovea), a privately-held French biopharmaceutical research and development company specializing in ophthalmology, acquired October 30, 2009. The purchase consideration is contingent on milestone payments linked to the development of three products for a maximum amount of 280 million at acquisition date. The amount of contingent consideration recognized in the balance sheet as at December 31, 2011 is disclosed in Note D.18. Liabilities related to business combinations and to non-controlling interests .

Oenobiol (November 2009), one of France's leading players in health and beauty dietary supplements.

Laboratorios Kendrick (March 2009), one of Mexico's leading manufacturers of generics.

Helvepharm (July 2009), a Swiss generics company.

## D.2. Merial

In March 2010, Sanofi exercised its contractual right to combine its Animal Health business (Merial) with that of Merck (Intervet/Schering-Plough) to form a new joint venture equally owned by Merck and Sanofi. Consequently, all of the assets and liabilities of Merial were reported respectively in the line items *Assets held for sale or exchange* and *Liabilities related to assets held for sale or exchange*, and the net income of Merial was reported in the line item Net income from the held for exchange Merial business, in accordance with IFRS 5 (see Note B.7.).

However, on March 22, 2011, Merck and Sanofi announced the end of the agreement to form a new joint venture in animal health and the decision to maintain two separate entities, Merial et Intervet/Schering-Plough, operating independently. This decision was primarily due to the complexity of implementing the proposed transaction, both in terms of the nature and extent of the anticipated divestitures and the length of time necessary for the worldwide regulatory review process.

As a result, Sanofi's stake in Merial is no longer presented separately in the consolidated balance sheet and income statement since January 1, 2011. In accordance with IFRS 5 (see Note B.7.), this change in accounting method has been treated as follows:

As of December 31, 2011, the assets and liabilities of Merial are reported in the relevant balance sheet line item, without restating the presentation of the balance sheet as of December 31, 2010.

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The net income from the Merial business presented in the line item Net income from the held for exchange Merial business in the previously published financial statements has been reclassified and included in the income from continuing operations for all periods reported.

Merial's assets have been valued since January 1, 2011 at their carrying amount before classification as assets held for sale, adjusted for any depreciation, amortization or impairment which would have been recognized if the asset had never been classified as held for sale.

The backlog of depreciation and amortization and impairment not recognized during the period from September 18, 2009 to December 31, 2010, amounts to \$519 million (see Note D.28.) and is reported in the income statement in the line item *Other gains and losses, and litigation*.

Depreciation and amortization from January 1, 2011 are presented in the income statement line corresponding to the type or use of the asset, based on the principles applied to continuing operations.

In addition, this decision also extinguished Sanofi's obligation to pay Merck \$250 million to establish parity in the joint venture, or to pay the additional consideration of \$750 million stipulated in the agreement signed on July 29, 2009.

The impacts related to the reclassification of the Merial net income for \$386 million at December 31, 2010 and \$175 million at December 31, 2009 in net income from continuing operations, in accordance with IFRS 5.36, are presented in the table below:

	At December 31,	At December 31,
( million)	2010	2009
<b>Net sales</b>	<b>1,983</b>	<b>479</b>
Other revenues	18	4
Cost of sales	(681)	(227)
<b>Gross profit</b>	<b>1,320</b>	<b>256</b>
Research and development costs	(146)	(43)
Selling and general expenses	(582)	(139)
Other operating income	10	1
Other operating expenses	(16)	(6)
Restructuring costs	(12)	
<b>Operating income</b>	<b>574</b>	<b>69</b>
Financial expenses	(1)	
Financial income	1	2
<b>Income before tax and associates and joint ventures</b>	<b>574</b>	<b>71</b>
Income tax expense	(188)	(35)
Share of profit/(loss) of associates and joint ventures <sup>(1)</sup>		139
<b>Net income</b>	<b>386</b>	<b>175</b>

<sup>(1)</sup> Until September 17, 2009



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Property, plant and equipment (including assets held under finance leases) comprise:

<i>( million)</i>	<b>Land</b>	<b>Buildings</b>	<b>Plant &amp; equipment</b>	<b>Fixtures, fittings &amp; other</b>	<b>Property, plant and equipment in process</b>	<b>Total</b>
Gross value at January 1, 2009	215	3,300	4,979	1,545	1,512	11,551
Changes in scope of consolidation	61	245	199	26	13	544
Acquisitions and other increases	1	32	87	63	1,170	1,353
Disposals and other decreases	(3)	(22)	(23)	(157)	(17)	(222)
Currency translation differences	6	26	24	5	4	65
Transfers	(5)	463	581	122	(1,348)	(187)
Gross value at December 31, 2009	275	4,044	5,847	1,604	1,334	13,104
Changes in scope of consolidation	1	29	15	5	7	57
Acquisitions and other increases	1	12	57	71	1,058	1,199
Disposals and other decreases	(3)	(14)	(12)	(124)	(153)	(153)
Currency translation differences	11	172	134	38	31	386
Transfers	(11)	312	482	76	(1,076)	(217)
Gross value at December 31, 2010	274	4,555	6,523	1,670	1,354	14,376
Merrial <sup>(1)</sup>	31	384	208	50	84	757
Changes in scope of consolidation	72	770	396	13	613	1,864
Acquisitions and other increases	5	28	111	82	1,214	1,440
Disposals and other decreases	(3)	(32)	(19)	(89)	(1)	(144)
Currency translation differences	4	60	(27)	(27)	45	82
Transfers	(8)	171	448	284	(1,060)	(165)
<b>Gross amounts at December 31, 2011</b>	<b>375</b>	<b>5,936</b>	<b>7,640</b>	<b>2,010</b>	<b>2,249</b>	<b>18,210</b>
Accumulated depreciation & impairment at January 1, 2009	(4)	(1,093)	(2,400)	(1,056)	(37)	(4,590)
Depreciation expense	(1)	(238)	(530)	(161)	(1)	(929)
Impairment losses	(4)	(73)	(22)	(4)	(5)	(108)
Disposals	2	12	24	148	2	188
Currency translation differences	(3)	(4)	(16)	(3)	(3)	(23)
Transfers	3	87	103	(5)	(5)	188
Accumulated depreciation & impairment at December 31, 2009	(3)	(1,309)	(2,841)	(1,081)	(40)	(5,274)
Depreciation expense	(1)	(298)	(623)	(167)	(1)	(1,088)
Impairment losses	(4)	(29)	12	(2)	(6)	(29)
Disposals	(1)	10	1	114	(1)	125
Currency translation differences	(1)	(66)	(67)	(24)	(1)	(157)
Transfers	5	140	42	11	4	202
Accumulated depreciation & impairment at December 31, 2010	(2)	(1,552)	(3,476)	(1,149)	(42)	(6,221)
Changes in scope of consolidation	(1)	24	18	12	(1)	54
Depreciation expense <sup>(2)</sup>	(1)	(362)	(700)	(199)	(1)	(1,261)
Impairment losses	(28)	(184)	(31)	(29)	(15)	(287)
Disposals	(1)	23	3	81	(1)	107
Currency translation differences	(1)	(10)	26	1	(1)	15
Transfers	12	151	54	(85)	1	133
<b>Accumulated depreciation &amp; impairment at December 31, 2011</b>	<b>(19)</b>	<b>(1,910)</b>	<b>(4,106)</b>	<b>(1,368)</b>	<b>(57)</b>	<b>(7,460)</b>
Carrying amount: January 1, 2009	211	2,207	2,579	489	1,475	6,961
Carrying amount: December 31, 2009	272	2,735	3,006	523	1,294	7,830
Carrying amount: December 31, 2010	272	3,003	3,047	521	1,312	8,155
<b>Carrying amount: December 31, 2011</b>	<b>356</b>	<b>4,026</b>	<b>3,534</b>	<b>642</b>	<b>2,192</b>	<b>10,750</b>

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- (1) This lines includes the Merial property, plant and equipment previously presented as **Assets held for sale or exchange**, which were reclassified following the announcement to maintain two separate entities (Merial and Intervet/Schering-Plough) operating independently.
- (2) Including the expense related to the backlog of amortization for 2009 and 2010 on Merial tangible assets, previously classified as **Assets held for sale or exchange** and presented in the line item **Other gains and losses, and litigation** in the income statement.

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The line item "Changes in scope of consolidation" in 2011 primarily represents the initial recognition of the tangible assets following the Genzyme acquisition for a total value of \$1,933 million (see Note D.1.1.).

The value of the tangible assets of the Dermik business disposed of in 2011 (see Note D.1.3.) is also presented in "Changes in scope of consolidation" for a net amount of \$35 million.

The "Transfers" line for the year ended December 31, 2011 mainly includes the reclassification of assets to *Assets held for sale or exchange*.

Property, plant and equipment pledged as security for liabilities amounted to \$239 million as of December 31, 2011 (\$26 million as of December 31, 2010 and \$15 million as of December 31, 2009).

In addition, the valuation of property, plant and equipment using the method described in Note B.6, led to the recognition of a \$287 million impairment loss for 2011 primarily related to research and development sites as part of the restructuring of this activity and an industrial site based in Slovakia. For 2010, an impairment loss of \$53 million for a site held for sale and an impairment loss reversal of \$24 million were recognized.

Acquisitions for 2011 represent investments made in the Pharmaceuticals segment, primarily investments in industrial facilities (\$510 million excluding Genzyme in 2011 versus \$471 million in 2010 and \$496 million in 2009) and in facilities and equipment at research sites (\$124 million in 2011, versus \$159 million in 2010 and \$325 million in 2009). Genzyme acquisitions since its acquisition date totaled \$218 million. In addition, acquisitions in the Vaccines segment totaled \$302 million (compared with \$423 million in 2010 and \$446 million in 2009). Assets acquired in the Animal Health segment totaled \$78 million in 2011. Capitalized borrowing costs amounted to \$44 million (\$27 million in 2010 and \$30 million in 2009). Firm orders for property, plant and equipment amounted to \$292 million at December 31, 2011 (\$321 million at December 31, 2010 and \$351 million at December 31, 2009).

The table below shows amounts for items of property, plant and equipment held under finance leases:

( million)	December 31, 2011	December 31, 2010	December 31, 2009
Land	7	7	7
Buildings	137	84	99
Other property, plant and equipment	17	15	6
<b>Total gross value</b>	<b>161</b>	<b>106</b>	<b>112</b>
Accumulated depreciation and impairment	(64)	(78)	(81)
<b>Carrying amount</b>	<b>97</b>	<b>28</b>	<b>31</b>

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Future minimum lease payments due under finance leases at December 31, 2011 were 123 million (versus 28 million at December 31, 2010 and 27 million at December 31, 2009), including interest of 30 million (versus 3 million at December 31, 2010 and 3 million at December 31, 2009).

The payment schedule is as follows:

December 31, 2011  ( million)	Payments due by period				Over 5 years
	Total	Under 1 year	From 1 to 3 years	From 3 to 5 years	
Finance lease obligations:					
principal	92	12	27	28	25
interest	31	7	13	7	4
<b>Total</b>	<b>123</b>	<b>19</b>	<b>40</b>	<b>35</b>	<b>29</b>

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.4. Goodwill and other intangible assets**

Other intangible assets break down as follows:

<i>( million)</i>	Acquired Aventis R&D	Other Acquired R&D	Rights to marketed Aventis products	Products, trademarks and other rights	Software	Total other intangible assets
Gross value at January 1, 2009	2,453	558	30,319	1,760	585	35,675
Changes in scope of consolidation		789		1,405	12	2,206
Acquisitions and other increases		275		62	56	393
Disposals and other decreases		(70)		(1)	(2)	(73)
Currency translation differences	(45)	(51)	(451)	47	2	(498)
Transfers	(87)	(9)	87	11	2	4
Gross value at December 31, 2009	2,321	1,492	29,955	3,284	655	37,707
Changes in scope of consolidation		192		1,365		1,557
Acquisitions and other increases		167		154	67	388
Disposals and other decreases		(7)		(3)	(9)	(19)
Currency translation differences	121	61	1,669	304	28	2,183
Transfers	(173)	(341)	173	389	(1)	47
Gross value at December 31, 2010	2,269	1,564	31,797	5,493	740	41,863
Merial <sup>(1)</sup>		674		3,235	70	3,979
Changes in scope of consolidation	(42)	2,235	(1,044)	8,122	38	9,309
Acquisitions and other increases		92		62	107	261
Disposals and other decreases		(13)		(9)	(2)	(24)
Currency translation differences	43	154	667	580	7	1,451
Transfers	(167)	(444)	167	450	11	17
<b>Gross value at December 31, 2011</b>	<b>2,103</b>	<b>4,262</b>	<b>31,587</b>	<b>17,933</b>	<b>971</b>	<b>56,856</b>
Accumulated amortization & impairment at Jan. 1, 2009	(1,484)	(47)	(17,399)	(997)	(488)	(20,415)
Amortization expense		(70)	(3,155)	(303)	(50)	(3,578)
Impairment losses, net of reversals		(28)	(344)			(372)
Disposals		69		2		71
Currency translation differences	28	2	288	19	(1)	336
Transfers		2		(4)		(2)
Accumulated amortization & impairment at Dec. 31, 2009	(1,456)	(72)	(20,610)	(1,283)	(539)	(23,960)
Amortization expense			(3,050)	(479)	(49)	(3,578)
Impairment losses, net of reversals	(10)	(132)	(117)	(174)		(433)
Disposals		5		3	9	17
Currency translation differences	(75)	(3)	(1,178)	(106)	(24)	(1,386)
Transfers	1	62		(108)	1	(44)
Accumulated amortization & impairment at Dec. 31, 2010	(1,540)	(140)	(24,955)	(2,147)	(602)	(29,384)
Changes in scope of consolidation	42		832	1	1	876
Amortization expense <sup>(2)</sup>			(1,754)	(1,972)	(107)	(3,833)
Impairment losses, net of reversals		(101)	34	(75)	(1)	(143)
Disposals		13		8	5	26
Currency translation differences	(33)	(6)	(591)	(119)	(2)	(751)
Transfers				(4)	(4)	(8)
<b>Accumulated amortization &amp; impairment at December 31, 2011</b>	<b>(1,531)</b>	<b>(234)</b>	<b>(26,434)</b>	<b>(4,308)</b>	<b>(710)</b>	<b>(33,217)</b>
Carrying amount: January 1, 2009	969	511	12,920	763	97	15,260
Carrying amount: December 31, 2009	865	1,420	9,345	2,001	116	13,747
Carrying amount: December 31, 2010	729	1,424	6,842	3,346	138	12,479
<b>Carrying amount: December 31, 2011</b>	<b>572</b>	<b>4,028</b>	<b>5,153</b>	<b>13,625</b>	<b>261</b>	<b>23,639</b>

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- (1) This line item includes the other Merial intangible assets previously presented as **Assets held for sale or exchange**, which were reclassified following the announcement to maintain two separate entities (Merial and Intervet/Schering-Plough) operating independently.
- (2) Including the expense related to the backlog of amortization for 2009 and 2010 on Merial intangible assets, previously classified as **Assets held for sale or exchange** and presented in the line item **Other gains and losses, and litigation** in the income statement.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Movements in goodwill for the last three financial periods are shown below:

<i>( million)</i>	<b>Gross value</b>	<b>Impairment</b>	<b>Carrying amount</b>
<b>Balance at January 1, 2009</b>	<b>28,188</b>	<b>(25)</b>	<b>28,163</b>
Movements for the period <sup>(1)</sup>	1,798		1,798
Currency translation differences	(228)		(228)
<b>Balance at December 31, 2009</b>	<b>29,758</b>	<b>(25)</b>	<b>29,733</b>
Movements for the period <sup>(1)</sup>	1,017		1,017
Currency translation differences	1,183	(1)	1,182
<b>Balance at December 31, 2010</b>	<b>31,958</b>	<b>(26)</b>	<b>31,932</b>
Merial goodwill <sup>(2)</sup>	1,210		1,210
Genzyme goodwill	4,086		4,086
Other movements for the period <sup>(1)</sup>	275		275
Currency translation differences	574	2	576
<b>Balance at December 31, 2011</b>	<b>38,103</b>	<b>(24)</b>	<b>38,079</b>

<sup>(1)</sup> Mainly relating to changes in the scope of consolidation.

<sup>(2)</sup> Previously reported in *Assets held for sale or exchange*, and reclassified following the announcement of the decision to maintain Merial and Intervet/Schering-Plough as two separate businesses operating independently.

**Genzyme acquisition (2011)**

The Genzyme provisional purchase price allocation resulted in the initial recognition of intangible assets totaling 10,063 million at the acquisition date (see Note D.1.1.). This figure includes 7,731 million for marketed products in the fields of rare diseases (primarily Cerezyme®, Fabrazyme® and Myozyme®), renal-endocrinology (primarily Renagel®), biosurgery (primarily SynVisc®), and oncology. It also includes 2,148 million for assets relating to Genzyme's in-process research and development projects primarily Lemtrada and eliglustat. The Genzyme brand was valued at 146 million.

**Merial control take-over (2009)**

When Sanofi took control of Merial in 2009, intangible assets were recognized for a total of 3,980 million, including 3,104 million related to marketed products, including Frontline®, 674 million relating to in-process research and development projects, and 131 million for the Merial brand.

In 2011, some of the acquired research and development (451 million) came into commercial use during the period, and is being amortized from the date of marketing approval. This was primarily Certifact® in the United States and the European Union.

**Aventis acquisition (2004)**

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On August 20, 2004, Sanofi acquired Aventis, a global pharmaceutical group created in 1999 by the merger between Rhône-Poulenc and Hoechst.

As part of the process of creating the new Group, the two former parent companies Sanofi-Synthélabo (renamed Sanofi) and Aventis were merged on December 31, 2004.

The total purchase price as measured under IFRS 3 (Business Combinations) was 52,908 million, of which 15,894 million was settled in cash.

Goodwill arising from the acquisition of Aventis amounted to 28,573 million at December 31, 2011 (compared with 28,228 million and 27,221 million at December 31, 2010 and December 31, 2009 respectively).

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Rights to marketed products and goodwill arising on the Aventis acquisition were allocated on the basis of the split of the Group's operations into business and geographical segments, and valued in the currency of the relevant geographical segment (mainly euros and U.S. dollars) with assistance from an independent valuer. The average period of amortization for marketed products was initially set at 8 years, based on cash flow forecasts which, among other factors, take account of the period of legal protection offered by the related patents.

Rights to marketed Aventis products represent a diversified portfolio of rights relating to many different products. As of December 31, 2011, 76.3% of the carrying amount of these rights related to the Pharmaceuticals segment, and 23.7% to the Vaccines segment. The five principal pharmaceutical products in this portfolio by carrying amount accounted for approximately 57.2% of the total carrying amount of product rights for the Pharmaceuticals business as of December 31, 2011.

During 2011, some of the Aventis acquired research and development (€ 167 million) came into commercial use and is being amortized from the date of marketing approval. This is primarily the oncology product Jevtana<sup>®</sup> (cabazitaxel) in the European Union.

In 2010, some of the acquired Aventis research and development (€ 173 million) came into commercial use. This was primarily the oncology drug Jevtana<sup>®</sup> (cabazitaxel) in the United States.

In 2009, some of the acquired Aventis research and development (€ 87 million) came into commercial use. This primarily represented Sculpt<sup>®</sup> in the United States.

**Other acquisitions**

As of December 31, 2011, the increase in goodwill and other intangible assets (excluding Genzyme and Merial), was primarily related to the acquisition of BMP Sunstone (see Note D.1.2.).

The acquisitions of intangible assets, excluding software and assets recognized in business combinations in 2011 amounted to € 154 million, primarily related to license agreements (see description of the principal agreements in Note D.21.).

Increases in goodwill and other intangible assets and during the year ended December 31, 2010 were mainly due to business combinations completed during the year. Details of the purchase price allocations for the principal acquisitions made during 2010 are provided in Note D.1.4. and generated the following impacts:

For Chattem, recognition of intangible assets for € 1,121 million. Goodwill was € 773 million.

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For TargeGen, recognition of intangible assets for 176 million.

The effects of the final purchase price allocations of the principal acquisitions of 2009 (see Note D.1.5.) were as follows:

Medley: recognition of intangible assets of 181 million, and goodwill of 376 million.

Zentiva: recognition of intangible assets of 976 million (mainly comprising the value of marketed products and of the Zentiva trademark), and of goodwill of 886 million (including the effect of buyouts of non-controlling interests during the period).

BiPar: valuation of the principal product under development, BSI-201, at 539 million as of the acquisition date.

Shantha: recognition of intangible assets of 374 million.

In 2010, acquired non-Aventis research brought into commercial use mainly comprised Zentiva generics in Eastern Europe, the Japanese encephalitis vaccine, and the Libertas<sup>®</sup> formulation of Actonel<sup>®</sup> in the United States.

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Acquisitions of intangible assets during 2009 (other than software and assets recognized in business combinations) totaled 337 million and related mainly to license agreements, including the collaboration agreements with Exelixis and Merrimack.

**Dermik sale (2011)**

The change in scope of consolidation line item includes the net book value of the other intangible assets related to the Dermik dermatology business sold to Valeant Pharmaceuticals International, Inc. for 212 million, and a decrease in goodwill related to this business amounting to 77 million.

Amortization of intangible assets is recognized in the income statement under *Amortization of intangible assets* except for amortization of software, which is recognized on the relevant line of the income statement according to the purpose for which the software is used:

( million)	Year ended December 31, 2011	Year ended December 31, 2010 <sup>(1)</sup>	Year ended December 31, 2009 <sup>(1)</sup>
Cost of sales	13	11	11
Research and development expenses	16	11	14
Selling and general expenses	55	26	24
Other gains and losses, and litigation <sup>(2)</sup>	18		
Other operating expenses	5	1	1
<b>Total</b>	<b>107</b>	<b>49</b>	<b>50</b>

<sup>(1)</sup> Excluding Merial

<sup>(2)</sup> See Note D.2.

**D.5. Impairment of intangible assets and property, plant and equipment****Goodwill**

The recoverable amount of cash generating units (CGUs) is determined by reference to the value in use of each CGU, based on discounted estimates of the future cash flows from the CGU in accordance with the policies described in Note B.6.1.

The allocation of goodwill at December 31, 2011 is shown below:

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<i>( million)</i>	<b>Pharmaceuticals: Europe</b>	<b>Pharmaceuticals: North America</b>	<b>Pharmaceuticals: Other Countries</b>	<b>Vaccines: USA</b>	<b>Vaccines: Other Countries</b>	<b>Animal Health</b>	<b>Group Total</b>
Goodwill	15,072	14,194	6,459	766	339	1,249	38,079

The provisional goodwill on Genzyme was allocated to the relevant CGUs in the Pharmaceuticals segment.

The goodwill generated with the Merial takeover was allocated to the Animal Health CGU.

Value in use of each CGU was determined by applying an after-tax discount rate to estimated future after-tax cash flows.

A separate discount rate is used for each CGU in order to take into account its specific economic conditions.

The rates used for the impairment test performed in 2011 were between 7.0% and 10.5% (notably Pharmaceuticals North America: 8.0% and Pharmaceuticals Europe: 8.5%); an identical value in use for the Group would be obtained by applying a unique 9% rate to all the CGUs.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The pre-tax discount rates applied to estimated pre-tax cash flows are calculated by iteration from the previously determined value in use. They range from 12.2% to 14.9%; the equivalent unique rate is approximately 13% for the Group.

The assumptions used in testing goodwill for impairment are reviewed annually. Apart from the discount rate, the principal assumptions used in 2011 were as follows:

The perpetual growth rates applied to future cash flows were in a range from 0% (in particular, for Europe and North America) to 2% for Pharmaceuticals CGUs, and from 1% to 3% for the Vaccines and Animal Health CGUs.

The Group also applies assumptions on the probability of success of its current research and development projects, and more generally on its ability to renew its product portfolio in the longer term.

Value in use (determined as described above) is compared with carrying amount, and this comparison is then subject to sensitivity analysis with reference to the two principal parameters (discount rate and perpetual growth rate).

Over all the CGUs, no impairment of the goodwill tested, before allocation of the Genzyme goodwill, would need to be recognized when the useful value is calculated by using either:

a discount rate that may be up to +2.5 points above the base rates used or;

a perpetual growth rate that could be as much as -5.5 points below the base rates used.

No impairment losses were recognized against goodwill in the years ended December 31, 2011, 2010, or 2009.

The use of a single discount rate of 9% on each CGU would not have materially changed the sensitivity analyses in 2011.

**Other intangible assets**

When there is evidence that an asset may have become impaired, its value in use is calculated by applying a post-tax discount rate to the estimated future post-tax cash flows from that asset. For the purposes of impairment testing, the tax cash flows relating to the asset are determined using a notional tax rate incorporating the notional tax benefit that would result from amortizing the asset if its value in use were regarded as its depreciable amount for tax purposes. Applying post-tax discount rates to post-tax cash flows gives the same values in use as would be obtained by applying pre-tax discount rates to pre-tax cash flows.

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The post-tax discount rates used in 2011 for impairment testing of other intangible assets in the Pharmaceuticals, Vaccines and Animal Health segments were obtained by adjusting the Group's Weighted Average Cost of Capital of 8% to reflect specific country and business risks, giving post-tax rates in a range from 9% to 13%.

In most cases, there are no market data that would enable fair value less costs to sell to be determined other than by means of a similar estimate based on future cash flows. Consequently, the recoverable amount is in substance equal to the value in use.

In 2011, the result of the impairment tests of other intangible assets (excluding software) resulted in the recognition of a 142 million net impairment loss. This includes:

the impairment of Pharmaceuticals research projects for 101 million, primarily as a result of the interruption of the Goiter research program and the end of research collaboration agreements; and

a net impairment loss of 41 million, reflecting the depreciation of various marketed products in the Pharmaceuticals segment and, the partial reversal of the depreciation recorded on Actonel<sup>®</sup>, as a result of the confirmation to maintain the terms of the collaboration agreement signed with Warner Chilcott (see Note C.2.).

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In 2010, impairment losses of 433 million were recognized based on the results of impairment testing of other intangible assets. These losses arose mainly on marketed products (291 million), including Actonel® (due to proposed amendments to the terms of the collaboration agreement with Warner Chilcott, see Note C.2.) and Shan5® (due to revised sales projections following requalification of the vaccine by the World Health Organization). Impairment losses recognized in respect of research projects totaled 142 million, and arose mainly from revisions to the development plan for BSI-201 following announcement of the initial results from the Phase III trial in triple-negative metastatic breast cancer and from decisions to halt development on some other projects.

In 2009, impairment losses of 372 million were recognized based on the results of impairment tests. These losses related mainly to the marketed products Actonel®, Benzaclin® and Nasacort®, and took account of changes in the competitive environment and the approval dates of generics.

**Property, plant and equipment**

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

**D.6. Investments in associates and joint ventures**

For definitions of the terms associate and joint venture, refer to Note B.1.

Investments in associates and joint ventures break down as follows:

( million)	% interest	December 31, 2011	December 31, 2010	December 31, 2009
Sanofi Pasteur MSD	50.0	313	343	407
InfraServ Höchst	31.2	87	92	95
Entities and companies managed by Bristol-Myers Squibb <sup>(1)</sup>	49.9	307	265	234
Financière des Laboratoires de Cosmétologie Yves Rocher	39.1		128	123
Other investments		100	96	96
<b>Total</b>		<b>807</b>	<b>924</b>	<b>955</b>

<sup>(1)</sup> Under the terms of the agreements with BMS (see Note C.1.), the Group's share of the net assets of entities majority-owned by BMS is recorded in *Investments in associates and joint ventures*.

Since November 2011, Sanofi no longer has a representative in the Board of Directors of Financière des Laboratoires de Cosmétologie Yves Rocher and, as a result of the loss of significant influence, no longer recognizes this interest using the equity method. This interest was recognized at December 31, 2011 in available-for-sale financial assets (see Note D.7.).

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The financial statements include arm's length commercial transactions between the Group and certain of its associates and joint ventures. The principal transactions of this nature are summarized below:

<i>( million)</i>	<b>2011</b>	<b>2010</b>	<b>2009</b>
Sales	526	541	517
Royalties <sup>(1)</sup>	1,292	1,324	1,179
Accounts receivable <sup>(1)</sup>	503	441	419
Purchases	236	227	247
Accounts payable	21	22	32
Other liabilities <sup>(1)</sup>	404	350	297

<sup>(1)</sup> These items mainly relate to entities and companies managed by BMS.

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Key financial indicators for associates and joint ventures, excluding the effects of purchase price allocations, are as follows:

( million)	Principal associates <sup>(1)</sup>			Principal joint ventures <sup>(2)</sup>		
	100% impact			Share held by Sanofi		
	2011	2010	2009	2011	2010	2009
Non-current assets	46	512	526	23	25	27
Current assets	679	1,336	1,278	195	231	224
Non-current liabilities	85	468	336	42	100	32
Current liabilities	512	690	792	164	142	178
Equity attributable to equity holders of Sanofi	128	387	391	12	14	41
Non-controlling interests		303	285			
Net sales	8,113	8,114	9,325	396	459	1,203
Cost of sales	2,118	2,130	2,397	171	179	359
Operating income	3,419	3,163	3,144	52	49	312
Net income	3,286	3,035	2,880	14	8	222

<sup>(1)</sup> The figures reported above are full-year figures, before allocation of partnership profits. Figures for Merial are not included in this table with effect from September 18, 2009 (the date since when Merial has been accounted for by the full consolidation method), and figures for Zentiva are not included in this table with effect from March 31, 2009 (the date since when Zentiva has been accounted for by the full consolidation method). The balance sheet balances for Yves Rocher are not included in this table for 2011.

<sup>(2)</sup> The principal joint ventures are:

	Partner	Business
Merial (until September 17, 2009)	Merck & Co., Inc.	Animal Health
Sanofi Pasteur MSD	Merck & Co., Inc.	Vaccines

**D.7. Non-current financial assets**

The main items included in *Non-current financial assets* are:

( million)	December 31, 2011	December 31, 2010	December 31, 2009
Available-for-sale financial assets	1,302	816	588
Pre-funded pension obligations (see Note D.19.1.)	6	4	3
Long-term loans and advances	573	483	256
Assets recognized under the fair value option	124	121	100
Derivative financial instruments (see Note D.20.)	394	220	51
<b>Total</b>	<b>2,399</b>	<b>1,644</b>	<b>998</b>

Equity investments classified as available-for-sale financial assets include the following publicly traded interests:

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An equity interest in the biopharmaceuticals company Regeneron, with which Sanofi has research and development collaboration agreements (see Note D.21.). This investment had a carrying amount of 678 million at December 31, 2011 ( 389 million at December 31, 2010 and 248 million at December 31, 2009).

A 4.66% equity interest in Nichi-Iko, valued on the basis of the quoted market price as of December 31, 2011, at 34 million.

Equity interests resulting from the Genzyme acquisition, primarily: Isis Pharmaceuticals (valued on the basis of the quoted market price as of December 31, 2011, at 28 million) and AbioMed Inc. (valued on the basis of the quoted market price as of December 31, 2011, at 13 million).

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Financial assets held to match commitments ( 272 million at December 31, 2011, 288 million at December 31, 2010, and 269 million at December 31, 2009).

The other comprehensive income recognized for available-for-sale financial assets represent unrealized net after-tax gain of 409 million (including 378 million for the investment in Regeneron) at December 31, 2011, 164 million at December 31, 2010 and 38 million at December 31, 2009.

The impact of a 10% fall in stock prices on quoted shares included in available-for-sale assets at December 31, 2011 would have been as follows:

<i>( million)</i>	<b>Sensitivity</b>
Other comprehensive income before tax	(89)
Income before tax	
<b>Total</b>	<b>(89)</b>

A 10% fall in stock prices of other available-for-sale financial assets combined with a simultaneous 0.5% rise in the yield curve would have had the following impact at December 31, 2011:

<i>( million)</i>	<b>Sensitivity</b>
Other comprehensive income before tax	(16)
Income before tax	
<b>Total<sup>(1)</sup></b>	<b>(16)</b>

<sup>(1)</sup> This impact would represent approximately 6% of the value of the underlying assets.

Available-for-sale financial assets also include equity investments not quoted in an active market. These investments had a carrying amount of 260 million at December 31, 2011, 47 million at December 31, 2010, and 31 million at December 31, 2009. The balance at December 31, 2011 also includes the interest in Financière des Laboratoires de Cosmétologie Yves Rocher (see Note D.6.).

The book value of Greek bonds as of December 31, 2011 was 30 million, including 23 million presented in current financial assets (see Note D.12.).

Long-term loans and advances are measured at amortized cost, which at the balance sheet date was not materially different from their fair value. The increase in long-term loans and advances in 2010 was mainly due to surety paid in connection with ongoing litigation.

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Assets recognized under the fair value option represent a portfolio of financial investments held to fund a deferred compensation plan offered to certain employees.

### D.8. Assets and liabilities held for sale or exchange

A breakdown as of December 31, 2011 of assets held for sale or exchange, and of liabilities related to assets held for sale or exchange, is shown below:

<i>( million)</i>		December 31, 2011	December 31, 2010	December 31, 2009
Merial <sup>(1)</sup>	D.8.1.		7,019	6,540
Other	D.8.2.	67	17	4
<b>Total assets held for sale or exchange</b>		<b>67</b>	<b>7,036</b>	<b>6,544</b>
Merial <sup>(1)</sup>	D.8.1.		1,672	1,501
Other	D.8.2.	20		
<b>Total liabilities related to assets held for sale or exchange</b>		<b>20</b>	<b>1,672</b>	<b>1,501</b>

<sup>(1)</sup> The Merial assets presented as assets held for sale or exchange in 2009 and 2010 were reclassified in 2011 to the relevant balance sheet line items in accordance with IFRS 5.26.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.8.1. Merial**

As explained in Note D.2., the assets and liabilities of Merial are no longer reported as held for sale or exchange, but instead are reported in the relevant balance sheet line item.

The table below shows the assets and liabilities of Merial classified in *Assets held for sale or exchange* and *Liabilities related to assets held for sale or exchange* at December 31, 2010 and 2009, after elimination of intercompany balances between Merial and other Group companies.

( million)	December 31, 2010	December 31, 2009 <sup>(1)</sup>
<b>Assets</b>		
Property, plant and equipment and financial assets	811	684
Goodwill	1,210	1,124
Other intangible assets	3,961	3,683
Deferred tax assets	92	60
Inventories	344	425
Accounts receivable	405	373
Other current assets	49	64
Cash and cash equivalents	147	127
<b>Total assets held for sale or exchange</b>	<b>7,019</b>	<b>6,540</b>
<b>Liabilities</b>		
Long-term debt	4	6
Non-current provisions	70	85
Deferred tax liabilities	1,132	1,034
Short-term debt	24	22
Accounts payable	161	124
Other current liabilities	281	230
<b>Total liabilities related to assets held for sale or exchange</b>	<b>1,672</b>	<b>1,501</b>

<sup>(1)</sup> In accordance with IFRS 3 (Business Combinations), Sanofi adjusted the values of certain identifiable assets and liabilities of Merial during the purchase price allocation period.

Changes in the balances relating to Merial between December 31, 2009 and December 31, 2010 were mainly due to translation effects arising from movements in the U.S. dollar exchange rate between those dates, and to adjustments to the purchase price allocation.

**D.8.2. Other assets held for sale**

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As of December 31, 2011, the assets held for sale were primarily the assets of the sub-group BMP Sunstone held for sale since the acquisition date, and the assets of research and development sites in France, and European industrial or tertiary sites.

As of December 31, 2010, other assets held for sale relate to R&D facilities in France.

As of December 31, 2009, other assets held for sale related to the ongoing divestment of the R&D facilities at Alnwick and Porcheville and of an industrial site. An impairment loss of 107 million was charged against these assets (and recognized under ***Restructuring costs*** in the income statement) prior to their reclassification as assets held for sale.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.9. Inventories**

Inventories break down as follows:

<i>( million)</i>	December 31, 2011			December 31, 2010			December 31, 2009		
	Gross	Impairment	Net	Gross	Impairment	Net	Gross	Impairment	Net
Raw materials	973	(93)	<b>880</b>	838	(88)	<b>750</b>	752	(96)	<b>656</b>
Work in process	3,444	(209)	<b>3,235</b>	2,940	(255)	<b>2,685</b>	2,456	(241)	<b>2,215</b>
Finished goods	2,107	(171)	<b>1,936</b>	1,714	(129)	<b>1,585</b>	1,709	(136)	<b>1,573</b>
<b>Total</b>	<b>6,524</b>	<b>(473)</b>	<b>6,051</b>	<b>5,492</b>	<b>(472)</b>	<b>5,020</b>	<b>4,917</b>	<b>(473)</b>	<b>4,444</b>

The value of inventories related to Genzyme was 925 million at the acquisition date (see note D.1.1.) and 540 million at December 31, 2011. The amount of the Merial inventories reclassified at January 1, 2011 was 344 million (see note D.8.1.).

The impact of changes in provisions for impairment of inventories is a net expense of 6 million in 2011, 22 million in 2010 and 26 million in 2009.

Impairment losses against inventories as of December 31, 2011 relate primarily to the product Ketek®.

Inventories pledged as security for liabilities amounted to 14 million at December 31, 2011.

**D.10. Accounts receivable**

Accounts receivable break down as follows:

<i>( million)</i>	December 31, 2011	December 31, 2010	December 31, 2009
Gross value	8,176	6,633	6,111
Impairment	(134)	(126)	(96)
<b>Net value</b>	<b>8,042</b>	<b>6,507</b>	<b>6,015</b>

The value of trade receivables related to Genzyme totaled 764 million at the acquisition date (see Note D.1.1.). Merial trade receivables, reclassified at January 1, 2011, amounted to 405 million (see Note D.8.1.).

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The net loss (including the impairment reversals) on accounts receivables (see Note B.8.2.) was a net expense of 32 million in 2011, identical to the amount recorded over 2010. A net loss of 5 million was booked in 2009.

The gross value of overdue receivables at December 31, 2011 was 1,103 million, compared with 887 million at December 31, 2010 and 884 million at December 31, 2009.

<i>( million)</i>	<b>Overdue accounts Gross value</b>	<b>Overdue &lt; 1 month</b>	<b>Overdue from 1 to 3 months</b>	<b>Overdue from 3 to 6 months</b>	<b>Overdue from 6 to 12 months</b>	<b>Overdue &gt; 12 months</b>
December 31, 2011	<b>1,103</b>	278	227	187	135	276
December 31, 2010	<b>887</b>	255	207	127	97	201
December 31, 2009	<b>884</b>	288	172	132	110	182

Amounts overdue by more than one month relate mainly to public-sector customers.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.11. Other current assets**

Other current assets break down as follows:

( million)	December 31, 2011	December 31, 2010	December 31, 2009
Taxes payable	1,455	1,188	1,019
Other receivables <sup>(1)</sup>	690	626	914
Prepaid expenses	256	186	171
<b>Total</b>	<b>2,401</b>	<b>2,000</b>	<b>2,104</b>

<sup>(1)</sup> This line mainly comprises amounts due from alliance partners, advance payments to suppliers, sales commission receivable, and amounts due from employees.

**D.12. Current financial assets**

Current financial assets break down as follows:

( million)	December 31, 2011	December 31, 2010	December 31, 2009
Interest rate derivatives measured at fair value (see Note D.20.)	90	1	18
Currency derivatives measured at fair value (see Note D.20.)	48	27	251
Other current financial assets	35 <sup>(1)</sup>	23	8
<b>Total</b>	<b>173</b>	<b>51</b>	<b>277</b>

<sup>(1)</sup> Including 23 million Greek bonds as of December 31, 2011 (see Note D.7.).

**D.13. Cash and cash equivalents**

( million)	December 31, 2011	December 31, 2010	December 31, 2009
Cash	1,029	696	689
Cash equivalents <sup>(1)</sup>	3,095	5,769	4,003
<b>Cash and cash equivalents <sup>(2)</sup></b>	<b>4,124</b>	<b>6,465</b>	<b>4,692</b>

<sup>(1)</sup>

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*Cash equivalents at December 31, 2011 mainly comprised (i) 1,879 million invested in collective investment schemes classified by AMF as Euro Money-Market Funds and Short-term Money-Market , and invested in Dollars Money-Market Funds compliant to rule 2a-7 SEC, (ii) 316 million of term deposits, (iii) 260 million of treasury notes, and (iv) 460 million held by captive insurance and reinsurance companies in accordance with insurance regulation.*

*(2) Includes 47 million held by the Venezuelan subsidiary at December 31, 2011, which is subject to foreign exchange controls.*

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.14. Net deferred tax position**

The net deferred tax position breaks down as follows:

<i>( million)</i>	<b>December 31, 2011</b>	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Deferred tax (excluding Genzyme) on:			
Consolidation adjustments (intragroup margin in inventory)	858	875	858
Provision for pensions and other employee benefits	1,298	1,157	1,097
Remeasurement of other acquired intangible assets <sup>(1)</sup>	(3,616)	(3,706)	(4,144)
Recognition of acquired property, plant and equipment at fair value	(64)	(76)	(99)
Equity interests in subsidiaries and investments in affiliate <sup>(2)</sup>	(661)	(399)	(643)
Tax losses available for carry-forward	524	152	70
Stock options	40	12	21
Expenses payable and provisions deductible at the time of payment <sup>(3)</sup>	1,493	1,349	985
Other	(71)	(121)	(166)
Net deferred tax liability related to Genzyme <sup>(4)</sup>	(2,179)		
<b>Net deferred tax liability</b>	<b>(2,378)</b>	<b>(757)</b>	<b>(2,021)</b>

<sup>(1)</sup> Includes deferred tax liabilities of 1,948 million at December 2011, relating to the remeasurement of Aventis intangible assets and 467 million for Merial.

<sup>(2)</sup> In some countries, the Group is liable to withholding taxes and other tax charges when dividends are distributed. Consequently, the Group recognizes a deferred tax liability on the reserves of foreign subsidiaries (approximately 19 billion) which the Group regards as likely to be distributed in the foreseeable future.

<sup>(3)</sup> This amount includes deferred tax assets related to the restructuring provisions in the amount of 433 million at December 31, 2011, 389 million at December 31, 2010 and 274 million at December 31, 2009.

<sup>(4)</sup> This amount primarily reflects the impact of the remeasurement at fair value of the intangible assets made for provisional allocation of the acquisition price (see note D.1.1.).

As of December 31, 2011, the reserves of the Sanofi subsidiaries, which are taxable in the event of distribution for which payments is not planned, and which did not result in the recognition of deferred tax liabilities, and for which payment is not planned, amounted to 15.7 billion, compared with 16.2 billion at December 31, 2010.

The table below shows when the tax losses available for carry-forward are due to expire:

<i>( million)</i>	<b>Tax losses available for carry-forward<sup>(1)</sup></b>
2012	15
2013	4
2014	24
2015	36
2016	37
2017 and later <sup>(2)</sup>	2,583
<b>Total at December 31, 2011</b>	<b>2,699</b>

<b>Total at December 31, 2010</b>	<b>1,028</b>
<b>Total at December 31, 2009</b>	<b>642</b>

*(1) Excluding tax loss carry-forwards on asset disposals. Tax loss carry-forwards on asset disposals amounted to zero at December 31, 2011 versus 101 million at December 31, 2010, and 597 million at December 31, 2009.*

*(2) Primarily composed of tax losses to be carried forward indefinitely.*

Use of these tax loss carry-forwards is limited to the entity in which they arose. In jurisdictions where tax consolidations are in place, tax losses can be netted against taxable income generated by the entities in the consolidated tax group.

Deferred tax assets not recognized because their future recovery was not regarded as probable given the expected results of the entities in question amounted to 476 million in 2011, 451 million in 2010 (including 35 million on asset disposals), compared with 486 million in 2009 (including 99 million on asset disposals).

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The effect of recognizing previously unrecognized deferred tax assets in accounting for business combinations (requiring a corresponding adjustment to goodwill) amounted to 88 million in 2009.

**D.15. Consolidated shareholders' equity****D.15.1. Share capital**

The share capital of 2,681,837,622 consists of 1,340,918,811 shares with a par value of 2.

Treasury shares held by the Group are as follows:

	Number of shares in million	%
December 31, 2011	17.2	1.28 %
December 31, 2010	6.1	0.46 %
December 31, 2009	9.4	0.71 %
January 1, 2009	10.0	0.76 %

Treasury shares are deducted from shareholders' equity. Gains and losses on disposals of treasury shares are taken directly to equity and not recognized in net income for the period.

Movements in the share capital of the Sanofi parent company over the last three years are presented below:

Date	Transaction	Number of shares	Share capital (1)	Additional paid-in capital (1)
<b>January 1, 2009</b>		<b>1,315,525,463</b>	<b>2,631</b>	<b>6,604</b>
During 2009	Capital increase by exercise of stock subscription options	2,953,589	6	134
<b>December 31, 2009</b>		<b>1,318,479,052</b>	<b>2,637</b>	<b>6,738</b>
During 2010	Capital increase by exercise of stock subscription options	430,033	1	17
Board of Directors meeting of April 28, 2010	Capital reduction by cancellation of treasury shares	(7,911,300)	(16)	(404)
<b>December 31, 2010</b>		<b>1,310,997,785</b>	<b>2,622</b>	<b>6,351</b>
During 2011		1,593,369	4	66

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	Capital increase by exercise of stock subscription options			
During 2011	Capital increase by issue of restricted shares	587,316	1	(1)
June 16, 2011	Capital increase by payment of dividends in shares	38,139,730	76	1,814
Board of Directors meeting of July 27, 2011	Capital reduction by cancellation of treasury shares	(2,328,936)	(5)	(116)
Board of Directors meeting of November 2, 2011	Capital reduction by cancellation of treasury shares	(8,070,453)	(16)	(372)
<b>December 31, 2011</b>		<b>1,340,918,811</b>	<b>2,682</b>	<b>7,742</b>

(1) million amounts.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

For equity related disclosures as required under IFRS 7, refer to Note B.27.

Following the exercise of Sanofi stock options, 1,593,369 shares were issued in the 2011 fiscal year.

In addition, 585,782 bonus shares under the 2009 France restricted share plan were vested and issued in 2011.

**D.15.2. Restricted share plans**

Restricted share plans are accounted for in accordance with the policies described in Note B.24.3.

The Board of Directors meeting held on March 9, 2011, approved a restricted share plan with performance conditions for 3,330,650 shares, including 1,934,610 shares vested at the end of a four-year service period, and 1,396,040 shares vested at the end of a two-year service period and then non-transferable for a two-year period. The fair value of a share awarded is the market price of the share as of the grant date ( 50.28), adjusted for the dividends expected during the vesting period.

The fair value of this restricted share plan is 125 million.

The Board of Directors meeting held on October 27, 2010 decided to award a worldwide restricted share plan, under which 20 shares were granted to each employee of the Group. The fair value per share granted is the market price of the share as of the date of grant ( 49.53), adjusted for expected dividends during the vesting period. A total of 2,101,340 shares were granted under this plan.

The fair value of this restricted share plan is 67 million.

The Board of Directors meeting held on March 1, 2010 decided to award a discretionary restricted share plan. A total of 1,231,249 shares were granted, 699,524 of which will vest after a four-year service period and 531,725 of which will vest after a two-year service period but will be subject to a further two-year lock-up period. The fair value per share granted is the market price of the share as of the date of grant ( 54.82), adjusted for expected dividends during the vesting period.

The fair value of this restricted share plan is 50 million.

The Board of Directors meeting held on March 2, 2009 decided to award a restricted share plan. A total of 1,194,064 shares were granted, 604,004 of which will vest after a four-year service period and 590,060 of which will vest after a two-year service period but

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will be subject to a further two-year lock-up period (including 65,000 shares which are also contingent upon performance conditions). The fair value per share granted is the market price per share as of the date of grant ( 41.10), adjusted for expected dividends during the vesting period.

The fair value of this restricted share plan is 37 million.

At December 31, 2011, the total expense for the restricted share plans amounted to 84 million compared with 36 million at December 31, 2010 and 11 million at December 31, 2009.

The number of restricted shares outstanding at December 31, 2011 was 7,062,324, including 3,266,840 under the plan approved in March 2011, 2,063,440 under the plan approved in October 2010, 1,176,038 under the plan approved in March 2010 and 556,006 under the 2009 plan. There were 4,467,968 restricted shares outstanding at December 31, 2010 and 1,181,049 at December 31, 2009.

### **D.15.3. Capital increase**

On May 6, 2011, the General Meeting of Sanofi shareholders approved the payment of a 2.50 dividend per share for the 2010 fiscal year, with an option for payment in cash or in newly-issued shares of the Company. As a result of the exercise of this option by shareholders representing 57.8% of the shares, 38,139,730 new shares were issued for payment of the dividend in shares. The shares issued represent 2.9% of the capital, which is an increase of 76 million in capital and 1,814 million in additional paid-in capital (net of transactions costs to issue dividends in shares).



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There were no share issues reserved for employee share ownership plans in 2009, 2010 or 2011.

**D.15.4. Repurchase of Sanofi shares**

The Sanofi Shareholders' Annual General Meeting of May 6, 2011 authorized a share repurchase program for a period of 18 months. Under this program, the Group repurchased 21,655,140 shares in 2011 for a total amount of 1,074 million.

The Sanofi Shareholders' Annual General Meeting of May 17, 2010 authorized a share repurchase program for a period of 18 months. The Group has not repurchased any of its own shares under this program.

Under the share repurchase program authorized by the Shareholders' Annual General Meeting of April 17, 2009, the Group repurchased 5,871,026 shares in 2010 for a total of 321 million.

There were no stock buybacks in 2009.

**D.15.5. Reduction in share capital**

The Board of Directors on November 2, 2011 approved the cancellation of 8,070,453 treasury shares ( 388 million), representing 0.60% of the share capital as of that date.

The Sanofi Board of Directors meeting held on July 27, 2011 decided to cancel 2,328,936 treasury shares ( 121 million), representing 0.17% of the share capital as of that date.

The Sanofi Board of Directors on April 28, 2010 decided to cancel 7,911,300 treasury shares ( 420 million), representing 0.60% of the share capital as of that date.

These cancellations had no effect on consolidated shareholders' equity.

**D.15.6. Currency translation differences**

Currency translation differences break down as follows:

<i>( million)</i>	<b>December 31, 2011</b>	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Attributable to equity holders of Sanofi	(1,374)	(1,318)	(3,962)
Attributable to non-controlling interests	(16)	(4)	(15)
<b>Total</b>	<b>(1,390)</b>	<b>(1,322)</b>	<b>(3,977)</b>

The movement in currency translation differences during the period was mainly due to the effect of changes in the U.S. dollar exchange rate, primarily on goodwill, intangible assets and inventories.

In accordance with the accounting policy described in Note B.8.4., currency translation differences *attributable to equity holders of Sanofi* include the post-tax effect of currency hedges of net investments in foreign operations, which amounted to 66 million after tax at December 31, 2011, 85 million after tax at December 31, 2010 and 86 million after tax at December 31, 2009.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.15.7. Other comprehensive income**

Movements in other comprehensive income are as follows:

( million)	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31, 2009
<b>Balance, beginning of period</b>	<b>(1,102)</b>	<b>(3,755)</b>	<b>(4,436)</b>
<i>Attributable to equity holders of Sanofi</i>	<i>(1,097)</i>	<i>(3,739)</i>	<i>(4,419)</i>
<i>Attributable to non-controlling interests</i>	<i>(5)</i>	<i>(16)</i>	<i>(17)</i>
Merial revaluation of previously held equity interest:			
Change in fair value <sup>(1)</sup>			1,379
Tax effects			(326)
Zentiva revaluation of previously held equity interest:			
Change in fair value <sup>(1)</sup>			108
Tax effects			(28)
Actuarial gains/(losses)			
Impact of asset ceiling		1	2
Actuarial gains/(losses) excluding associates, joint ventures and Merial	(677)	(316)	(169)
Actuarial gains/(losses) on associates and joint ventures		(1)	(2)
Actuarial gains/(losses) on Merial		5	
Tax effects	138	172	36
<b>Items that cannot be reclassified to profit or loss</b>	<b>(539)</b>	<b>(139)</b>	<b>1,000</b>
Available-for-sale financial assets:			
Change in fair value <sup>(2)</sup>	250	141	110
Tax effects	(5)	(15)	(23)
Cash flow hedges:			
Change in fair value <sup>(3)</sup>	5	17	(175)
Tax effects	(2)	(6)	61
Change in currency translation differences			
Currency translation differences on foreign subsidiaries <sup>(4)</sup>	(49)	2,656	(280)
Hedges of net investments in foreign operations	(30)	(2)	(18)
Tax effects	11	1	6
<b>Items that may be reclassified to profit or loss</b>	<b>180</b>	<b>2,792</b>	<b>(319)</b>
<b>Balance, end of period</b>	<b>(1,461)</b>	<b>(1,102)</b>	<b>(3,755)</b>
<i>Attributable to equity holders of Sanofi</i>	<i>(1,444)</i>	<i>(1,097)</i>	<i>(3,739)</i>
<i>Attributable to non-controlling interests</i>	<i>(17)</i>	<i>(5)</i>	<i>(16)</i>

(1) Fair value remeasurement of the previously held equity interest (24.9% for Zentiva and 50% for Merial) as of the date when control was acquired.

(2) Including reclassification to the income statement: not significant in 2011, 2010 and 2009.

(3) Including reclassification to the income statement: not significant in 2011, 7 million in 2010 in operating income versus ( 123) million in 2009, and 2 million in 2011 in net financial expense versus 5 million in 2010 and ( 35) million in 2009.

(4) Includes a reclassification to the income statement of 1 million in 2011 versus 3 million in 2010.

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**D.15.8. Share-based payment**

**Stock option plans**

**a) Assumption by Sanofi of the obligations of Aventis**

*Stock subscription option plans*

With effect from December 31, 2004, Sanofi substituted for Aventis in all the rights and obligations of the issuer in respect of stock subscription options granted to employees and former corporate officers of Aventis and of related companies (as defined in article L.225-180 of the Commercial Code) and not exercised as of that date.

With effect from December 31, 2004, stock subscription options granted by Aventis and not yet exercised may be exercised in Sanofi shares on the same terms, subject to the adjustments described below. The number and subscription price of the optioned shares have been adjusted to reflect the share exchange ratio applicable to Aventis shareholders, subject to possible further adjustment in the event of future capital transactions. The new terms for the exercise of options, subject to future financial adjustments, are as follows:

The number of Sanofi shares for which each grantee may subscribe under a given stock option plan equals the number of Aventis shares to which the grantee may subscribe under that plan multiplied by the exchange ratio applicable to the shareholders (i.e. 27/23), rounded down to the nearest whole number.

The subscription price per Sanofi share equals the subscription price per Aventis share divided by the exchange ratio applicable to the shareholders (i.e. 27/23), rounded down to the nearest euro cent.

**b) Description of stock option plans**

*2011 stock subscription option plan*

On March 9, 2011, the Board of Directors granted 874,500 stock subscription options at an exercise price of 50.48 per share.

The vesting period is four years, and the plan expires on March 9, 2021.

*2010 stock subscription option plan*

On March 1, 2010, the Board of Directors granted 8,121,355 stock subscription options at an exercise price of \$54.12 per share.

The vesting period is four years, and the plan expires on February 28, 2020.

*2009 stock subscription option plan*

On March 2, 2009, the Board of Directors granted 7,736,480 stock subscription options at an exercise price of \$45.09 per share.

The vesting period is four years, and the plan expires on March 2, 2019.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Stock purchase option plans*

The table shows all Sanofi stock purchase option plans still outstanding or under which options were exercised in the year ended December 31, 2011.

<b>Origin</b>	<b>Date of grant</b>	<b>Options granted</b>	<b>Start date of exercise period</b>	<b>Expiration date</b>	<b>Exercise price ( )</b>	<b>Options outstanding at December 31, 2011</b>
Synthélabo	12/15/1993	364,000	12/15/1998	12/15/2013	6.36	
Synthélabo	10/18/1994	330,200	10/18/1999	10/18/2014	6.01	5,700
Synthélabo	01/12/1996	208,000	01/12/2001	01/12/2016	8.56	14,070
Synthélabo	04/05/1996	228,800	04/05/2001	04/05/2016	10.85	29,470
Synthélabo	10/14/1997	262,080	10/14/2002	10/14/2017	19.73	28,242
Synthélabo	06/25/1998	296,400	06/26/2003	06/25/2018	28.38	4,100
Synthélabo	03/30/1999	716,040	03/31/2004	03/30/2019	38.08	263,745
Sanofi-Synthélabo	05/10/2001	2,936,500	05/11/2005	05/10/2011	64.50	
Sanofi-Synthélabo	05/22/2002	3,111,850	05/23/2006	05/22/2012	69.94	2,858,750
<b>Total</b>						<b>3,204,077</b>

Sanofi shares acquired to cover stock purchase options are deducted from shareholders' equity. The exercise of all outstanding stock purchase options would increase shareholders' equity by 211 million.

*Stock subscription option plans*

Details of the terms of exercise of stock subscription options granted under the various plans are presented below in Sanofi share equivalents. These options have been granted to certain corporate officers and employees of Group companies.

The table shows all Sanofi stock subscription option plans still outstanding or under which options were exercised in the year ended December 31, 2011.

<b>Origin</b>	<b>Date of grant</b>	<b>Options granted</b>	<b>Start date of exercise period</b>	<b>Expiration date</b>	<b>Exercise price ( )</b>	<b>Options outstanding at December 31, 2011</b>
Aventis	03/29/2001	612,196	03/30/2004	03/29/2011	68.94	
Aventis	11/07/2001	13,374,051	11/08/2004	11/07/2011	71.39	
Aventis	03/06/2002	1,173,913	03/07/2005	03/06/2012	69.82	1,173,906

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Aventis	11/12/2002	11,775,414	11/13/2005	11/12/2012	51.34	4,671,543
Aventis	12/02/2003	12,012,414	12/03/2006	12/02/2013	40.48	4,114,243
Sanofi-Synthélabo	12/10/2003	4,217,700	12/11/2007	12/10/2013	55.74	3,801,470
Sanofi-aventis	05/31/2005	15,228,505	06/01/2009	05/31/2015	70.38	13,196,960
Sanofi-aventis	12/14/2006	11,772,050	12/15/2010	12/14/2016	66.91	10,710,140
Sanofi-aventis	12/13/2007	11,988,975	12/14/2011	12/13/2017	62.33	11,044,430
Sanofi-aventis	03/02/2009	7,736,480	03/04/2013	03/01/2019	45.09	7,244,710
Sanofi-aventis	03/01/2010	8,121,355	03/03/2014	02/28/2020	54.12	7,726,085
Sanofi-aventis	03/09/2011	874,500	03/10/2015	03/09/2021	50.48	844,500
<b>Total</b>						<b>64,527,987</b>

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The exercise of all outstanding stock subscription options would increase shareholders' equity by approximately 3,821 million. The exercise of each option results in the issuance of one share.

*Summary of stock option plans*

A summary of stock options outstanding at each balance sheet date, and of changes during the relevant periods, is presented below:

	Number of options	Weighted average per share ( )	Exercise price ( million)	Total ( million)
Options outstanding at January 1, 2009	85,304,950	62.66		5,345
<i>Options exercisable</i>	<i>48,713,680</i>	<i>59.59</i>		<i>2,903</i>
Options granted	7,736,480	45.09		349
Options exercised	(3,545,344)	46.69		(165)
Options cancelled <sup>(1)</sup>	(1,000,535)	61.72		(62)
Options forfeited	(625,210)	48.89		(31)
Options outstanding at December 31, 2009	87,870,341	61.87		5,436
<i>Options exercisable</i>	<i>57,717,316</i>	<i>63.04</i>		<i>3,638</i>
Options granted	8,121,355	54.12		440
Options exercised	(1,756,763)	42.50		(75)
Options cancelled <sup>(1)</sup>	(1,269,312)	59.56		(75)
Options forfeited	(10,694,693)	67.21		(719)
Options outstanding at December 31, 2010	82,270,928	60.86		5,007
<i>Options exercisable</i>	<i>55,663,453</i>	<i>63.63</i>		<i>3,542</i>
Options granted	874,500	50.48		44
Options exercised	(1,679,029)	43.11		(72)
Options cancelled <sup>(1)</sup>	(1,137,052)	57.64		(66)
Options forfeited	(12,597,283)	69.90		(880)
Options outstanding at December 31, 2011	67,732,064	59.54		4,033
<i>Options exercisable</i>	<i>51,916,769</i>	<i>62.51</i>		<i>3,245</i>

<sup>(1)</sup> Cancellations mainly due to the departure of the grantees.

The table below provides summary information about options outstanding and exercisable as of December 31, 2011:

Range of exercise prices per share	Outstanding			Exercisable	
	Number of options	Average residual life (in years)	Weighted average exercise price per share ( )	Number of options	Weighted average exercise price per share ( )
From 1.00 to 10.00 per share	19,770	3.68	7.83	19,770	7.83



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From 10.00 to 20.00 per share	57,712	5.01	15.19	57,712	15.19
From 20.00 to 30.00 per share	4,100	6.49	28.38	4,100	28.38
From 30.00 to 40.00 per share	263,745	7.25	38.08	263,745	38.08
From 40.00 to 50.00 per share	11,358,953	5.27	43.42	4,114,243	40.48
From 50.00 to 60.00 per share	17,043,598	4.83	53.54	8,473,013	53.31
From 60.00 to 70.00 per share	25,787,226	4.66	65.42	25,787,226	65.42
From 70.00 to 80.00 per share	13,196,960	3.42	70.38	13,196,960	122.54
<b>Total</b>	<b>67,732,064</b>			<b>51,916,769</b>	

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Measurement of stock option plans*

The fair value of the plan awarded in 2011 is \$6 million. This amount is recognized as an expense over the vesting period, with the matching entry to shareholders' equity. On this basis, an expense of \$1 million was recognized in the year ended December 31, 2011.

The fair value of the plan awarded in 2010 was \$66 million.

The following assumptions were used in determining the fair value of these plans:

Dividend yield: 5.12% (2011 plan) and 4.66% (2010 plan).

Volatility of Sanofi shares, computed on a historical basis: 26.93% for the 2011 plan and 27.08% for the 2010 plan.

Risk-free interest rate: 3.05% (2011 plan) and 2.56% (2010 plan).

Plan maturity: 6 years (2011 and 2010 plans). The plan maturity is the average expected remaining life of the options, based on observations of past employee behavior.

The fair value of the options granted in 2011 and 2010 is \$7.88 and \$9.09 per option, respectively.

The expense recognized for stock option plans, and the matching entry taken to shareholders' equity, was \$59 million for 2011 (including \$6 million for the Vaccines segments) compared with \$97 million for 2010 (including \$10 million for the Vaccines segment), and \$102 million in 2009 (including \$12 million for the Vaccines segment).

As of December 31, 2011, the total cost related to non-vested stock option plans was \$51 million, to be recognized over a weighted average period of 2 years. The current tax benefit related to the exercise of stock options in 2011 is \$2.2 million (\$1 million in 2010 and \$2 million in 2009).

**D.15.9. Number of shares used to compute diluted earnings per share**

Diluted earnings per share is computed using the number of shares outstanding plus stock options with a potentially dilutive effect.

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<i>(in millions)</i>	<b>December 31, 2011</b>	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Average number of shares outstanding	1,321.7	1,305.3	1,305.9
Adjustment for options with potentially dilutive effect	1.7	1.7	1.1
Adjustment for restricted shares with potentially dilutive effect	3.3	1.2	0.4
<b>Average number of shares used to compute diluted earnings</b>			
<b>per share</b>	<b>1,326.7</b>	<b>1,308.2</b>	<b>1,307.4</b>

In 2011, a total of 56 million stock options were not taken into account in the calculation of diluted earnings because they did not have a potentially dilutive effect, compared with 69.1 million stock options in 2010 and 80.3 million in 2009.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.16. Non-controlling interests**

Non-controlling interests in consolidated companies break down as follows:

( million)	December 31, 2011	December 31, 2010	December 31, 2009
<b>Non-controlling interests of ordinary shareholders:</b>			
BMS <sup>(1)</sup>	34	41	104
Zentiva	21	28	32
Aventis Pharma Ltd India	58	75	73
Maphar	7	7	7
Sanofi-aventis Korea	7	7	5
Shantha Biotechnics	10	9	12
Other	33	24	25
<b>Total</b>	<b>170</b>	<b>191</b>	<b>258</b>

<sup>(1)</sup> Under the terms of the agreements with BMS (see Note C.1.), the BMS share of the net assets of entities majority-owned by Sanofi is recognized in Non-controlling interests (refer to the statement of changes in equity).

**D.17. Debt, cash and cash equivalents**

The table below shows changes in the Group's financial position over the last three years:

( million)	December 31, 2011	December 31, 2010	December 31, 2009
Long-term debt	12,499	6,695	5,961
Short-term debt and current portion of long-term debt	2,940	1,565	2,866
Interest rate and currency derivatives used to hedge debt	(483)	(218)	(7)
<b>Total debt</b>	<b>14,956</b>	<b>8,042</b>	<b>8,820</b>
Cash and cash equivalents	(4,124)	(6,465)	(4,692)
Interest rate and currency derivative instruments used to hedge cash and cash equivalents	27		
<b>Debt, net of cash and cash equivalents</b>	<b>10,859</b>	<b>1,577</b>	<b>4,128</b>

Debt, net of cash and cash equivalents is a non-GAAP financial indicator used by management and investors to measure the company's overall net indebtedness.

Trends in the gearing ratio are shown below:

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<i>( million)</i>	December 31, 2011	December 31, 2010	December 31, 2009
Debt, net of cash and cash equivalents	10,859	1,577	4,128
Total equity	56,389	53,288	48,580
<b>Gearing ratio</b>	<b>19.3%</b>	<b>3.0%</b>	<b>8.5%</b>

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A reconciliation of carrying amount to value on redemption is shown below:

	Carrying			Value on redemption December 31,		
	amount:	Amortized	Adjustment to debt measured at fair value	2011	2010	2009
( million)	Dec. 31, 2011	cost				
Long-term debt	12,499	54	(275)	12,278	6,683	5,943
Short-term debt and current portion of long-term debt	2,940		(3)	2,937	1,565	2,853
Interest rate and currency derivatives used to hedge debt	(483)		225	(258)	(192)	8
<b>Total debt</b>	<b>14,956</b>	<b>54</b>	<b>(53)</b>	<b>14,957</b>	<b>8,056</b>	<b>8,804</b>
Cash and cash equivalents	(4,124)			(4,124)	(6,465)	(4,692)
Interest rate and currency derivative instruments used to hedge cash and cash equivalents	27		(3)	24		
<b>Debt, net of cash and cash equivalents</b>	<b>10,859</b>	<b>54</b>	<b>(56)</b>	<b>10,857</b>	<b>1,591</b>	<b>4,112</b>

**a) Principal financing transactions during the year**

The financing transactions in 2011 were as follows:

**Financing operations related to the Genzyme acquisition for \$20.4 billion:**

The Genzyme acquisition was financed as follows:

a bond issue in the United States for \$7 billion;

the issue of US Commercial Paper for \$7 billion;

a drawdown on a bridge facility for \$4 billion;

the use of available cash for \$2.4 billion.

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In March 2011, the Group issued a bond for a total amount of \$7 billion in six tranches:

\$1 billion in bonds maturing March 2012, bearing interest at the \$ 3-month Libor rate +0.05%;

\$1 billion in bonds maturing March 2013, bearing interest at the \$ 3-month Libor rate +0.20%;

\$750 million in bonds maturing March 2014, bearing interest at the \$ 3-month Libor rate +0.31%;

\$750 million in bonds maturing March 2014, bearing interest at an annual rate of 1.625%;

\$1.5 billion in bonds maturing March 2016, bearing interest at an annual rate of 2.625%;

\$2 billion in bonds maturing March 2021, bearing interest at an annual rate of 4%.

This bond issue was performed under a public bond issue program (shelf registration statement) registered with the US Securities and Exchange Commission (SEC).

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In addition, in the context of the launch of the tender offer for Genzyme, the Group contracted on October 2, 2010, two credit facilities totaling \$15 billion that could be used until July 2, 2011:

Facility A was a \$10 billion facility expiring April 2, 2012, with an optional six-month extension.

Facility B was a \$5 billion amortizable facility expiring April 2, 2014.

These acquisition facilities were not subject to any financial covenants. The margin of facility B was dependent on the long term credit rating of Sanofi subsequent to the acquisition.

On March 29, 2011, Facility A was reduced by the proceeds from the bond issue in the United States (for the amount of \$7 billion). The residual amount of this facility was cancelled on April 1, 2011.

On April 5, 2011, the Group drew \$4 billion on Facility B and cancelled the residual amount (\$1 billion).

On June 28, 2011, the Group prepaid \$1 billion on the draw from Facility B.

On August 5, 2011, the Group prepaid \$1 billion on the draw from Facility B.

On November 3, 2011, the Group prepaid the remaining \$2 billion drawn on Facility B.

In addition, as a result of the Genzyme acquisition, two bond tranches previously issued by Genzyme are included in the liabilities on the Group's consolidated balance sheet:

\$500 million in bonds maturing June 2015, bearing interest at an annual rate of 3.625%;

\$500 million in bonds maturing June 2020, bearing interest at an annual rate of 5%.

At the end of a procedure to request approval consent solicitation, these bonds are now secured by the parent company.



**Financing transactions related to the company's current operations:**

In September 2011, the Group completed a bond issue for \$1 billion, maturing in September 2014 and bearing interest at an annual rate of 1.2%.

No bond expired in 2011.

On November 3, 2011 the group contracted the following:

A new general-purpose syndicated credit facility with 14 banks for the amount of 3 billion, maturing December 26, 2012, with two options for an extension of one-year each. This new facility, effective since December 28, 2011, replaces an existing facility of 5.8 billion which was cancelled on December 28, 2011;

A one-year extension, renewable once, on the maturity of its 7 billion facility. Fourteen banks agreed to extend their commitment, for a total of 6.275 billion, maturing in July 2016. Two banks refused the extension, for a total commitment of 0.725 billion, thus retaining their initial maturity of July 2015.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****b) Debt, net of cash and cash equivalents by type, at value on redemption**

( million)	December 31, 2011			December 31, 2010			December 31, 2009		
	Non-current	Current	Total	Non-current	Current	Total	Non-current	Current	Total
Bond issues	11,662	1,324	<b>12,986</b>	5,879	92	<b>5,971</b>	5,236	1,982	<b>7,218</b>
Other bank borrowings	522	562	<b>1,084</b>	771	402	<b>1,173</b>	678	529	<b>1,207</b>
Commercial paper		695	<b>695</b>		735	<b>735</b>			
Finance lease obligations	80	12	<b>92</b>	19	6	<b>25</b>	15	9	<b>24</b>
Other borrowings	14	62	<b>76</b>	14	57	<b>71</b>	14	16	<b>30</b>
Bank credit balances		282	<b>282</b>		273	<b>273</b>		317	<b>317</b>
Interest rate and currency derivatives used to hedge debt	(143)	(115)	<b>(258)</b>	(194)	2	<b>(192)</b>	(53)	61	<b>8</b>
<b>Total debt</b>	<b>12,135</b>	<b>2,822</b>	<b>14,957</b>	<b>6,489</b>	<b>1,567</b>	<b>8,056</b>	<b>5,890</b>	<b>2,914</b>	<b>8,804</b>
Cash and cash equivalents		(4,124)	<b>(4,124)</b>		(6,465)	<b>(6,465)</b>		(4,692)	<b>(4,692)</b>
Interest rate and derivative instruments used to hedge cash and cash equivalents		24	<b>24</b>						
<b>Debt, net of cash and cash equivalents</b>	<b>12,135</b>	<b>(1,278)</b>	<b>10,857</b>	<b>6,489</b>	<b>(4,898)</b>	<b>1,591</b>	<b>5,890</b>	<b>(1,778)</b>	<b>4,112</b>

Bond issues made by the Holding Company under the EMTN (Euro Medium Term Notes) program comprise:

June 2008 issue of ¥15 billion ( 150 million), maturing June 2013, bearing interest at a floating rate indexed to 3-month JPY Libor, and swapped into euros at a floating rate indexed to 3-month Euribor;

May 2009 issue [ISIN: XS0428037666] of 1.5 billion, maturing May 2013, bearing annual interest at 3.5%;

May 2009 issue [ISIN: XS0428037740] of 1.5 billion, maturing May 2016, bearing annual interest at 4.5%;

October 2009 issue [ISIN: XS0456451938] of 1.2 billion (including supplementary tranche issued in April 2010), maturing October 2014, bearing annual interest at 3.125%;

October 2009 issue [ISIN: XS0456451771] of 800 million, maturing October 2019, bearing annual interest at 4.125%.

Bond issues made by the Holding Company under the public bond issue program (shelf registration statement) registered with the US Securities and Exchange Commission (SEC) comprise:

Bonds issued in March 2011 [ISIN: US80105NFA24] in the amount of \$1 billion, maturing March 2012 and bearing interest at the USD 3-month Libor rate +0.05%;

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Bonds issued in March 2011 [ISIN: US80105NAE58] in the amount of \$1 billion, maturing March 2013, and bearing interest at the USD 3-month Libor rate +0.20%;

Bonds issued in March 2011 [ISIN: US80105NAC92] in the amount of \$750 million, maturing March 2014, bearing interest at the USD 3-month Libor rate +0.31%;

Bonds issued in March 2011 [ISIN: US80105NAB10] in the amount of \$750 million, maturing March 2014, bearing interest at an annual rate of 1.625% ;

Bonds issued in March 2011 [ISIN: US80105NAD75] in the amount of \$1.5 billion, maturing March 2016, bearing interest bearing interest at an annual rate of 2.625%;

Bonds issued in March 2011 [ISIN: US80105NAG07] in the amount of \$2 billion, maturing March 2021, bearing interest at an annual rate of 4%;

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Bonds issued in September 2011 [ISIN: US801060AA22] in the amount of \$1 billion, maturing September 2014, bearing interest at an annual rate of 1.2%.

The issues in US dollars have been retained in this currency and have not been swapped into euros.

Bond issues made by the Holding Company outside the EMTN (Euro Medium Term Notes) and outside the US program (shelf registration statement) comprise:

December 2007 and February 2008 issues [ISIN: CH0035703070] of CHF400 million ( 329 million), maturing December 2015, bearing annual interest at 3.375%, and swapped into euros at a fixed rate of 4.867%;

December 2008 and January 2009 issues [ISIN: CH0048787532] amounting to CHF525 million ( 432 million), maturing December 2012, bearing annual interest at 3.26%, and swapped into euros as follows: CHF275 million at a fixed rate of 4.894%, and CHF250 million at a floating rate indexed to 3-month Euribor.

Bond issues made by Genzyme Corp. comprise:

Bonds issued in June 2010 [ISIN: US372917AQ70] for \$500 million, maturing June 2015, bearing annual interest at 3.625%;

Bonds issued in June 2010 [ISIN: US372917AS37] for \$500 million, maturing June 2020, bearing annual interest of 5%.

The line Other borrowings mainly includes:

Participating shares issued between 1983 and 1987, of which 93,903 remain outstanding (after cancellation in March 2011 of 3,080 shares previously repurchased in 2010), for a total of 14.5 million;

Series A participating shares issued in 1989, of which 3,271 remain outstanding, valued at 0.2 million.

In order to manage its liquidity needs for current operations, the Group now has:

A syndicated credit facility of 3 billion, maturing December 26, 2012, that may be drawn down in euros. This credit facility has two extension options for one year each;

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A syndicated credit facility of 7 billion expiring on July 6, 2015 for 0.725 billion, and expiring July 4, 2016 for 6.275 billion, that may also be drawn down in euros or U.S. dollars. This credit facility has an option for a one-year extension.

The Group owns two commercial paper programs of 6 billion in France and \$10 billion in the United States. In 2011, the average drawdown under these programs was 3.4 billion (maximum 6.2 billion). A total of 0.7 billion was drawn down under these facilities as of December 31, 2011.

The financing in place at December 31, 2011 at the level of the Holding Company (which manages most of the Group's financing needs centrally) is not subject to any financial covenants, and contains no clauses linking credit spreads or fees to the credit rating.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****c) Debt by maturity, at value on redemption**

December 31, 2011	Current			Non-current			2017 and later
	Total	2012	2013	2014	2015	2016	
( million)							
Bond issues	12,986	1,324	2,423	3,133	720	2,659	2,727
Other bank borrowings	1,084	562	482	15	8	9	8
Commercial paper <sup>(1)</sup>	695	695					
Finance lease obligations	92	12	14	13	14	14	25
Other borrowings	76	62					14
Bank credit balances	282	282					
Interest rate and currency derivatives used to hedge debt	(258)	(115)	(58)		(85)		
<b>Total debt</b>	<b>14,957</b>	<b>2,822</b>	<b>2,861</b>	<b>3,161</b>	<b>657</b>	<b>2,682</b>	<b>2,774</b>
Cash and cash equivalents	(4,124)	(4,124)					
Interest rate and currency derivative instruments used to hedge cash and cash equivalents	24	24					
<b>Debt, net of cash and cash equivalents</b>	<b>10,857</b>	<b>(1,278)</b>	<b>2,861</b>	<b>3,161</b>	<b>657</b>	<b>2,682</b>	<b>2,774</b>

<sup>(1)</sup> Commercial paper had a maturity of no more than four months as of December 31, 2011.

December 31, 2010	Current			Non-Current			2016 and later
	Total	2011	2012	2013	2014	2015	
( million)							
Bond issues	5,971	92	420	1,638	1,200	321	2,300
Other bank borrowings	1,173	402	203	555	6	7	
Commercial paper <sup>(1)</sup>	735	735					
Finance lease obligations	25	6	6	5	3	3	2
Other borrowings	71	57					14
Bank credit balances	273	273					
Interest rate and currency derivatives used to hedge debt	(192)	2	(73)	(46)		(75)	
<b>Total debt</b>	<b>8,056</b>	<b>1,567</b>	<b>556</b>	<b>2,152</b>	<b>1,209</b>	<b>256</b>	<b>2,316</b>
Cash and cash equivalents	(6,465)	(6,465)					
<b>Debt, net of cash and cash equivalents</b>	<b>1,591</b>	<b>(4,898)</b>	<b>556</b>	<b>2,152</b>	<b>1,209</b>	<b>256</b>	<b>2,316</b>

<sup>(1)</sup> Commercial paper had a maturity of no more than six months as of December 31, 2010.

December 31, 2009	Current			Non-Current			2015 and later
	Total	2010	2011	2012	2013	2014	
( million)							
Bond issues	7,218	1,982		354	1,613	700	2,569
Other bank borrowings	1,207	529	11	225	433	7	2
Commercial paper							
Finance lease obligations	24	9	3	3	3	3	3
Other borrowings	30	16					14

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Bank credit balances	317	317					
Interest rate and currency derivatives used to hedge debt	8	61		(7)	(20)		(26)
<b>Total debt</b>	<b>8,804</b>	<b>2,914</b>	<b>14</b>	<b>575</b>	<b>2,029</b>	<b>710</b>	<b>2,562</b>
Cash and cash equivalents	(4,692)	(4,692)					
<b>Debt, net of cash and cash equivalents</b>	<b>4,112</b>	<b>(1,778)</b>	<b>14</b>	<b>575</b>	<b>2,029</b>	<b>710</b>	<b>2,562</b>

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2011, the main undrawn confirmed general-purpose credit facilities at parent company level were as follows:

Year of expiry	Undrawn confirmed credit facilities available ( million)
2012	3,000
2015	725
2016	6,275
<b>Total</b>	<b>10,000</b>

As of December 31, 2011, no single counterparty represented more than 7% of undrawn confirmed credit facilities.

**d) Debt by interest rate, at value on redemption**

The tables below split debt, net of cash and cash equivalents between fixed and floating rate, and by maturity or contractual repricing date, at December 31, 2011. The figures shown are the value on redemption, before the effects of derivative instruments:

( million)	December 31, 2011						2017 and later
	Total	2012	2013	2014	2015	2016	
Fixed-rate debt	11,049	632	1,758	2,553	720	2,659	2,727
EUR	5,458						
USD	4,831						
<b>% fixed-rate</b>	<b>74%</b>						
Floating-rate debt (maturity based on contractual repricing date)	3,908	3,908					
EUR	312						
USD	3,010						
<b>% floating-rate</b>	<b>26%</b>						
Framed-rate debt (maturity based on contractual repricing date)							
EUR							
USD							
<b>% framed rate</b>							
<b>Total debt</b>	<b>14,957</b>	<b>4,540</b>	<b>1,758</b>	<b>2,553</b>	<b>720</b>	<b>2,659</b>	<b>2,727</b>
Cash and cash equivalents	(4,100)	(4,100)					
EUR	(2,005)						
USD	(1,521)						
<b>% floating-rate</b>	<b>100%</b>						
<b>Debt, net of cash and cash equivalents</b>	<b>10,857</b>	<b>440</b>	<b>1,758</b>	<b>2,553</b>	<b>720</b>	<b>2,659</b>	<b>2,727</b>



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Following the financing of the Genzyme acquisition, the Group manages its net debt in two currencies, the euro and the US dollar. The variable portion of this debt exposes the Group to an increase in interest rates, on the one hand on the Eonia and Euribor benchmarks and on the other hand on the US Libor and Federal Fund Effective.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In order to reduce the amount and/or volatility of the cost of debt, Sanofi has contracted derivative instruments (interest rate swaps, multi-currency interest rate swaps and interest rate options). This has the effect of altering the fixed/floating split and the maturity based on contractual repricing dates:

<i>( million)</i>	December 31, 2011						2017 and later
	Total	2012	2013	2014	2015	2016	
Fixed-rate debt	<b>6,726</b>	<b>427</b>	<b>1,758</b>	<b>966</b>	<b>720</b>	<b>1,159</b>	<b>1,696</b>
EUR	2,515						
USD	4,212						
<i>% fixed-rate</i>	<b>45%</b>						
Floating-rate debt	<b>6,299</b>	<b>6,299</b>					
EUR	3,949						
USD	1,672						
<i>% floating-rate</i>	<b>42%</b>						
Framed-rate date	<b>1,932</b>	<b>1,932</b>					
EUR							
USD	1,932						
<i>% framed rate</i>	<b>13%</b>						
<b>Total debt</b>	<b>14,957</b>	<b>8,658</b>	<b>1,758</b>	<b>966</b>	<b>720</b>	<b>1,159</b>	<b>1,696</b>
Cash and cash equivalents	<b>(4,100)</b>	<b>(4,100)</b>					
EUR	(3,380)						
USD	(146)						
<i>% floating-rate</i>	<b>100%</b>						
<b>Debt, net of cash and cash equivalents</b>	<b>10,857</b>	<b>4,558</b>	<b>1,758</b>	<b>966</b>	<b>720</b>	<b>1,159</b>	<b>1,696</b>

The table below shows the fixed/floating rate split at redemption value after taking account of derivative instruments as of December 31, 2010 and 2009:

<i>( million)</i>	2010	%	2009	%
Fixed-rate debt	5,350	66%	5,940	67%
Floating-rate debt	2,706	34%	2,864	33%
<b>Total debt</b>	<b>8,056</b>	<b>100%</b>	<b>8,804</b>	<b>100%</b>
Cash and cash equivalents	(6,465)		(4,692)	
<b>Debt, net of cash and cash equivalents</b>	<b>1,591</b>		<b>4,112</b>	

The weighted average interest rate on debt at December 31, 2011 was 2.9% before and 2.6% after derivative instruments. All cash and cash equivalents were invested at an average rate of 1.0% as of December 31, 2011.

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Based on the Group's level of debt, and taking account of derivative instruments in place as of December 31, 2011, sensitivity to movements in market interest rates over a full year would be as follows in the year ending December 31, 2012:

	Impact on pre-tax net income ( million)	Impact on income/(expense) recognized directly in equity, before tax ( million)
<b>Change in 3-month Euribor interest rate assumptions</b>		
+ 100 bp	(33)	(4)
+ 25 bp	(9)	(1)
- 25 bp	10	1
- 100 bp	41	(5)

**e) Debt, net of cash and cash equivalents by currency, at value on redemption**

The table below shows debt, net of cash and cash equivalents by currency at December 31, 2011, before and after taking account of derivative instruments contracted to convert third-party debt into the functional currency of the borrower entity:

( million)	December 31, 2011	
	Before derivative instruments	After derivative instruments
EUR	3,783	3,084
USD	6,343	7,717
CHF	582	
JPY	93	
Other currencies	56	56
<b>Debt, net of cash and cash equivalents</b>	<b>10,857</b>	<b>10,857</b>

The table below shows debt, net of cash and cash equivalents by currency at December 31, 2010 and 2009, after taking account of derivative instruments contracted to convert third-party debt into the functional currency of the borrower entity:

( million)	2010	2009
EUR	1,581	4,312
USD	37	(22)
GBP	(65)	(58)
Other currencies	38	(120)
<b>Debt, net of cash and cash equivalents</b>	<b>1,591</b>	<b>4,112</b>

**f) Market value of debt, net of cash and cash equivalents**

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The market value of debt, net of cash and cash equivalents as of December 31, 2011 was 11,596 million (compared with 1,887 million as of December 31, 2010 and 4,349 million as of December 31, 2009) for a value on redemption of 10,857 million as of December 31, 2011 (versus 1,591 million as of December 31, 2010 and 4,112 million as of December 31, 2009).

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****g) Future contractual cash flows relating to debt and debt hedging instruments**

The table below shows the amount of future contractual undiscounted cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as of December 31, 2011:

	December 31, 2011						
	Contractual cash flows by maturity						
( million)	Total	2012	2013	2014	2015	2016	2017 and later
<b>Debt</b>	<b>16,726</b>	<b>3,193</b>	<b>3,184</b>	<b>3,426</b>	<b>877</b>	<b>2,852</b>	<b>3,194</b>
principal	14,748	2,783	2,814	3,134	639	2,654	2,724
interest <sup>(1)</sup>	1,978	410	370	292	238	198	470
<b>Net cash flows related to derivative instruments</b>	<b>(231)</b>	<b>(72)</b>	<b>(66)</b>	<b>(48)</b>	<b>(21)</b>	<b>(28)</b>	<b>4</b>
<b>Total</b>	<b>16,495</b>	<b>3,121</b>	<b>3,118</b>	<b>3,378</b>	<b>856</b>	<b>2,824</b>	<b>3,198</b>

<sup>(1)</sup> Interest cash flows are estimated on the basis of forward interest rates applicable as of December 31, 2011.

Future contractual cash flows are shown on the basis of the carrying amount in the balance sheet at the reporting date, without reference to any subsequent management decision that might materially alter the structure of the Group's debt or its hedging policy.

Maturities used for credit facility drawdowns are those of the facility, not the drawdown.

The table below shows the amount of future contractual undiscounted cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as of December 31, 2010 and 2009:

	December 31, 2010						
	Contractual cash flows by maturity						
( million)	Total	2011	2012	2013	2014	2015	2016 and later
<b>Debt</b>	<b>9,354</b>	<b>1,699</b>	<b>875</b>	<b>2,418</b>	<b>1,360</b>	<b>462</b>	<b>2,540</b>
principal	8,150	1,447	632	2,200	1,208	347	2,316
interest <sup>(1)</sup>	1,204	252	243	218	152	115	224
<b>Net cash flows related to derivative instruments</b>	<b>(229)</b>	<b>(5)</b>	<b>(83)</b>	<b>(49)</b>	<b>3</b>	<b>(89)</b>	<b>(6)</b>
<b>Total</b>	<b>9,125</b>	<b>1,694</b>	<b>792</b>	<b>2,369</b>	<b>1,363</b>	<b>373</b>	<b>2,534</b>

<sup>(1)</sup> Interest cash flows are estimated on the basis of forward interest rates applicable as of December 31, 2010.

**December 31, 2009**  
**Contractual cash flows by maturity**

<i>( million)</i>	<b>Total</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015 and later</b>
<b>Debt</b>	<b>10,118</b>	<b>3,049</b>	<b>231</b>	<b>797</b>	<b>2,254</b>	<b>844</b>	<b>2,943</b>
principal	8,681	2,737	6	570	2,052	709	2,607
interest <sup>(1)</sup>	1,437	312	225	227	202	135	336
<b>Net cash flows related to derivative instruments</b>	<b>(14)</b>	<b>51</b>	<b>8</b>	<b>(9)</b>	<b>(24)</b>	<b>2</b>	<b>(42)</b>
<b>Total</b>	<b>10,104</b>	<b>3,100</b>	<b>239</b>	<b>788</b>	<b>2,230</b>	<b>846</b>	<b>2,901</b>

<sup>(1)</sup> Interest cash flows are estimated on the basis of forward interest rates applicable as of December 31, 2009.

#### **D.18. Liabilities related to business combinations and non-controlling interests**

For a description of the nature of liabilities reported in the line item *Liabilities related to business combinations and to non-controlling interests*, refer to Note B.8.5. The principal acquisitions are described in Note D.1.

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Obligations relating to business combinations mainly comprise contingent consideration in the form of milestone payments payable to the vendor and linked to development on projects conducted by the acquiree. The accounting treatment of contingent consideration is described in Note B.3.1. With effect from January 1, 2010, the fair value of contingent consideration in respect of products under development factors in (i) the probability that the project will succeed and (ii) the time value of money.

Movements in liabilities related to business combinations and to non-controlling interests were as follows:

<i>( million)</i>	Year ended December 31, 2011	Year ended December 31, 2010
<b>Balance, beginning of period</b>	<b>486</b>	<b>151</b>
split as follows:		
non-current	388	75
current	98	76
New business combinations	1,141	219
Payments made	(99)	(52)
Fair value remeasurement (including unwinding of discount)	(19)	5
Other movements	(5)	155
Currency translation differences	52	8
<b>Balance, end of period</b>	<b>1,556</b>	<b>486</b>
split as follows:		
non-current	1,336	388
current	220	98

New business combinations in the period mainly comprise:

481 million representing the fair value at the acquisition date of the CVRs issued by Sanofi in the context of the Genzyme acquisition (see Note D.1.1.).

585 million representing the fair value estimated at the acquisition date of the liability related to the Bayer contingent consideration resulting from the Genzyme acquisition (see Note D.1.1.).

Fair value remeasurements for 2011 are as follows:

<i>( million)</i>	December 31, 2011
<b>Fair value remeasurements recognized in income statement (gain) / loss<sup>(1)</sup></b>	<b>(15)</b>
<i>Including:</i>	
CVRs issued in connection with the acquisition of Genzyme	(211)
Bayer contingent consideration resulting from the acquisition of Genzyme	127
Other <sup>(2)</sup>	69

Other fair value remeasurements <sup>(3)</sup>	(4)
<b>Total fair value remeasurements for the year 2011</b>	<b>(19)</b>

<sup>(1)</sup> Amounts reported in the income statement line item *fair value remeasurements of contingent consideration liabilities*.

<sup>(2)</sup> Contingent consideration related to the TargeGen acquisition.

<sup>(3)</sup> Primarily represents the changes in fair value of the liabilities related to put options granted to non-controlling interests.

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The balance of these liabilities at the end of each period breaks down as follows:

( million)	December 31, 2011	December 31, 2010
Liabilities related to non-controlling interests <sup>(1)</sup>	133	134
Liabilities related to business combinations	1,423	352
Including:		
CVRs issued in connection with the acquisition of Genzyme <sup>(2)</sup>	268	
Bayer contingent consideration resulting from the acquisition of Genzyme	694	
Other	461	352
<b>Balance, end of period</b>	<b>1,556</b>	<b>486</b>

<sup>(1)</sup> Primarily put options granted to non-controlling interests.

<sup>(2)</sup> On the basis of the listed value of one CVR of \$1.2 at December 31, 2011.

The put options reported above were granted to non-controlling interests in connection with acquisitions completed during 2010, and relate to Sanofi-Aventis Vostok and Hangzhou Sanofi Minsheng Consumer Healthcare Co. Ltd (see Note D.1.4.).

Other liabilities related to business combinations as of December 31, 2011 mainly comprise contingent consideration related to the acquisitions of TargeGen ( 159 million), Fovea ( 151 million), and BiPar ( 74 million).

The table below sets forth the maximum amount of contingent consideration payable:

( million)	Total	December 31, 2011 Payments due by period			
		Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years
Obligations related to business combinations <sup>(1)</sup>	5,578	496	1,144	718	3,220

<sup>(1)</sup> Of which Bayer contingent consideration for 1.9 billion and 2.9 billion of CVRs issued as part of Genzyme acquisition.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.19. Provisions and other liabilities**

Provisions and other non-current liabilities break down as follows:

<i>( million)</i>	<b>Provisions for pensions and other benefits (D.19.1.)</b>	<b>Restructuring provisions (D.19.2.)</b>	<b>Other provisions (D.19.3.)</b>	<b>Other non-current liabilities</b>	<b>Total</b>
<b>January 1, 2009</b>	<b>4,068</b>	<b>366</b>	<b>3,084</b>	<b>212</b>	<b>7,730</b>
Changes in scope of consolidation	13		228	9	250
Increases in provisions and other liabilities	683	183	1,256 <sup>(2)</sup>		2,122
Provisions utilized	(603)	(61)	(251)	(10)	(925)
Reversals of unutilized provisions	(130)	(1)	(753) <sup>(3)</sup>	(24)	(908)
Transfers <sup>(1)</sup>	133	(232)	(104)	(70)	(273)
Unwinding of discount		3	36	1	40
Unrealized gains and losses				(12)	(12)
Currency translation differences	9	(1)	37	(2)	43
Actuarial gains/losses on defined-benefit plans <sup>(4)</sup>	169				169
<b>December 31, 2009</b>	<b>4,342</b>	<b>257</b>	<b>3,533</b>	<b>104</b>	<b>8,236</b>
Changes in scope of consolidation	21		27		48
Increases in provisions and other liabilities	442	731	857 <sup>(2)</sup>	11	2,041
Provisions utilized	(587)	(65)	(386)	(41)	(1,079)
Reversals of unutilized provisions	(82)	(56)	(259) <sup>(3)</sup>		(397)
Transfers <sup>(1)</sup>	(305)	119	81	(7)	(112)
Unwinding of discount		27	34	1	62
Unrealized gains and losses			(35)	33	(2)
Currency translation differences	96	4	108	5	213
Actuarial gains/losses on defined-benefit plans <sup>(4)</sup>	316				316
<b>December 31, 2010</b>	<b>4,243</b>	<b>1,017</b>	<b>3,960</b>	<b>106</b>	<b>9,326</b>
Merical <sup>(5)</sup>	64		48	4	116
Changes in scope of consolidation	35		150	20	205
Increases in provisions and other liabilities	414	500	470 <sup>(2)</sup>	15	1,399
Reversals of utilized provisions	(510)	(29)	(138)		(677)
Reversals of unutilized provisions	(97)	(19)	(363) <sup>(3)</sup>		(479)
Transfers <sup>(1)</sup>	(3)	(327)	(23)	(9)	(362)
Unwinding of discount	1	38	40		79
Unrealized gains and losses			1	(27)	(26)
Currency translation differences	68	2	13	5	88
Actuarial gains/losses on defined-benefit plans <sup>(4)</sup>	677				677
<b>December 31, 2011</b>	<b>4,892</b>	<b>1,182</b>	<b>4,158</b>	<b>114</b>	<b>10,346</b>

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- (1) This line includes transfers between current and non-current provisions, and in 2010 the reclassification of social security charges and Fillon levies on early retirement plans in France (see Note D.19.1.).*
- (2) Amounts charged during the period mainly comprise provisions to cover tax exposures in various countries and changes to estimate of future expenditure on environmental risks.*
- (3) Reversals relate mainly to provisions for tax exposures, reversed either because (i) the risk exposure became time-barred during the reporting period or (ii) the tax dispute was settled during the period and the outcome proved more favorable than expected for Sanofi.*
- (4) Amounts recognized as other comprehensive income (see Note D.15.7.).*
- (5) This line item includes the provisions and other non-current liabilities of Merial, previously presented as Liabilities on assets held for sale or exchange, which were reclassified following the announcement to maintain two separate entities (Merial and Intervet/Schering-Plough) operating independently (see note D.2.).*

Other current liabilities are described in Note D.19.4.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.19.1. Provisions for pensions and other benefits**

The Group and its subsidiaries have a significant number of pension plans covering the majority of their employees. The specific features (benefit formulas, funding policies and types of assets held) of the plans vary depending on laws and regulations in the particular country in which the employees work. Several of these plans are defined-benefit plans and cover some members of the Board of Directors as well as employees.

Actuarial valuations of the Group's benefit obligations were computed by management with assistance from external actuaries as of December 31, 2011, 2010, and 2009. These calculations incorporate the following elements:

Assumptions on staff turnover and life expectancy, specific to each country.

A retirement age of 60 to 67 for a total working life allowing for full-rate retirement rights for employees of French companies, and retirement assumptions reflecting local economic and demographic factors specific to employees of foreign companies.

A salary inflation rate for the principal countries ranging from 3% to 5% at December 31, 2011, 2010 and 2009.

An annuity inflation rate for the principal countries ranging from 2% to 5% at December 31, 2011, 2010 and 2009.

A weighted average long-term healthcare cost inflation rate of 4.58% at December 31, 2011, versus a weighted average rate of 4.51% at December 31, 2010 and 4.34% at December 31, 2009 applied to post-employment benefits.

Inflation rate assumptions, as shown in the table below:

<b>Inflation rate</b>	<b>2011</b>	<b>2010</b>	<b>2009</b>
Euro zone	2%	2%	2%
United States	2.75%	2.75%	3%
United Kingdom	3%	3.25%	3.1%

Discount rates used to determine the present value of defined benefit obligations at the balance sheet date, as shown in the table below:

<b>Discount rate</b>	<b>Pensions and other long-term benefits</b>			<b>Other post-employment benefits</b>		
	<b>Year ended December 31</b>			<b>Year ended December 31</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>	<b>2011</b>	<b>2010</b>	<b>2009</b>
Weighted average for all regions:	4.61%	4.97%	5.34%	4.62%	5.45%	5.76%

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Euro zone	4.25% or 4.75% <sup>(1)</sup>	4.25% or 4.75%	4.5% or 5.25%	4.75%	4.75%	5.25%
United States	4.5%	5.5%	5.75%	4.5%	5.5%	5.75%
United Kingdom	5%	5.5%	5.75%	5%	5.5%	5.75%

<sup>(1)</sup> Depends on the term of the plan: 4.25% medium-term, 4.75% long-term.

The discount rates used are based on market rates for high quality corporate bonds (AA) the term of which approximates that of the expected benefit payments of the plans.

Sensitivity analysis of pension plans and other post-employment benefits in the principal countries shows that a 0.5% reduction in discount rates would increase the Group's obligation by approximately 630 million, of which approximately 195 million would relate to the United Kingdom, 160 million to Germany, 115 million to France and 160 million to the United States.

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Assumptions about the expected long-term rates of return for plan assets. The majority of fund assets are invested in Germany, the United States and the United Kingdom. The expected long-term rates of return used are as follows:

Expected long-term rate of return on plan assets	Pensions and other long-term benefits			Other post-employment benefits					
	Year ended December 31			Year ended December 31					
	2011	2010	2009	2011	2010	2009			
Range of rates of return:	1.7%	12.5%	1.7%	14%	2%	13.5%	6.75%	7.5%	8%
Weighted average for all regions:	6.24%	6.48%	6.86%	6.75%	7.5%	8%			
Germany	6.25%	6.25%	6.75%						
United States	6.75%	7.5%	8%	6.75%	7.5%	8%			
United Kingdom	6%	6.25%	6.5%						

The average long-term rates of return on plan assets were determined on the basis of actual long-term rates of return in the financial markets. These returns vary according to the asset category (equities, bonds, real estate, other). As a general rule, Sanofi applies the risk premium concept in assessing the return on equities relative to bond yields.

An analysis of the sensitivity of the benefit cost to changes in the expected long-term rate of return on plan assets shows that a 0.5% reduction in the rate of return would increase the benefit cost by approximately 30 million.

The weighted average allocation of funds invested in Group pension plans is shown below:

Asset category (percentage)	Funds invested		
	2011	2010	2009
Equities	47%	50%	51%
Bonds	49%	47%	46%
Real estate	2%	2%	1%
Cash	2%	1%	2%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

The target allocation of funds invested as of December 31, 2011 is not materially different from the actual allocation as of December 31, 2010 and December 31, 2009.

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The table below reconciles the net obligation in respect of the Group's pension plans and other employee benefits with the amounts recognized in the consolidated financial statements:

( million)	Pensions and other long-term benefits			Other post-employment benefits (healthcare cover)		
	2011	2010 <sup>(1)</sup>	2009 <sup>(1)</sup>	2011	2010 <sup>(1)</sup>	2009 <sup>(1)</sup>
<b>Valuation of obligation:</b>						
Beginning of period	9,559	8,924	7,742	429	376	368
Merital	207			1		
Service cost	265	240	218	13	14	16
Contributions from plan members		5	4			
Interest cost	458	454	446	22	22	21
Actuarial (gain)/loss	366	593	759	23	22	1
Plan amendments		15	219			
Currency translation differences	169	259	64	13	27	(6)
Plan curtailments/settlements	(80)	(69)	(131)	(8)	(13)	(4)
Changes in scope of consolidation, transfers	105	(283) <sup>(2)</sup>	145		1	
Benefits paid	(574)	(579)	(542)	(23)	(20)	(20)
<b>Obligation at end of period</b>	<b>10,475</b>	<b>9,559</b>	<b>8,924</b>	<b>470</b>	<b>429</b>	<b>376</b>
<b>Fair value of plan assets:</b>						
Beginning of period	5,661	4,876	3,957	51	44	41
Merital	144					
Expected return on plan assets	367	347	278	3	4	3
Difference between actual and expected return on plan assets	(290)	252	547	(2)	3	6
Currency translation differences	113	185	49	1	4	(2)
Contributions from plan members	9	5	4			
Employer's contributions	331	400	405	3	1	1
Plan settlements	(4)	(1)	(5)			
Changes in scope of consolidation, transfers	73	5				
Benefits paid	(409)	(408)	(359)	(6)	(5)	(5)
<b>Fair value of plan assets at end of period</b>	<b>5,995</b>	<b>5,661</b>	<b>4,876</b>	<b>50</b>	<b>51</b>	<b>44</b>
<b>Net amount shown in the balance sheet:</b>						
Net obligation	4,480	3,898	4,048	420	378	332
Unrecognized past service cost	(23)	(45)	(49)	8	7	6
Effect of asset ceiling	1	1	2			
<b>Net amount shown in the balance sheet</b>	<b>4,458</b>	<b>3,854</b>	<b>4,001</b>	<b>428</b>	<b>385</b>	<b>338</b>
<b>Amounts recognized in the balance sheet:</b>						
Pre-funded obligations (see Note D.7.)	(6)	(4)	(3)			
Obligations provided for <sup>(3)</sup>	4,464	3,858	4,004	428	385	338
<b>Net amount recognized</b>	<b>4,458</b>	<b>3,854</b>	<b>4,001</b>	<b>428</b>	<b>385</b>	<b>338</b>
<b>Benefit cost for the period:</b>						
Service cost	256	240	218	13	14	16
Interest cost	458	454	446	22	22	21
Expected return on plan assets	(367)	(347)	(278)	(3)	(4)	(3)
Amortization of past service cost	21	20	224			
Recognition of actuarial (gains)/losses	4	44	38			
Effect of plan curtailments	(77)	(69)	(122)	(8)	(13)	(4)
Effect of plan settlements	1		(3)			
<b>Benefit cost for the period</b>	<b>296</b>	<b>342</b>	<b>523</b>	<b>24</b>	<b>19</b>	<b>30</b>

<sup>(1)</sup> Excluding Merital, for which the net amounts recognized on the balance sheet were presented as assets and liabilities held for sale or exchange at December 31, 2010 and 2009.

<sup>(2)</sup> Includes a reduction of 322 million in respect of social security charges and Fillon levies due on early retirement plans in France, which were provided for as part of the pension obligation at December 31, 2009 but were reclassified as restructuring provisions at December 31, 2010; these provisions also include the portion relating to annuities (see Note D.19.2.).

<sup>(3)</sup>

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*Long-term benefits awarded to employees prior to retirement (mainly discretionary bonuses, long service awards and deferred compensation plans) accounted for 483 million at December 31, 2011, 445 million at December 31, 2010, 371 million at December 31, 2009. The expense associated with these obligations totaled 56 million at December 31, 2011, 106 million in 2010, 84 million in 2009.*

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Actuarial gains and losses on pensions, other long-term and post-employment benefits break down as follows:

( million)	2011	2010	2009	2008	2007
Actuarial gains/(losses) arising during the period <sup>(1)</sup>	(681)	(360)	(207)	(786)	289
Comprising:					
gains/(losses) on experience adjustments	(266)	169	531	(1,326)	(135)
gains/(losses) on changes in assumptions <sup>(2)</sup>	(415)	(529)	(738)	540	424
Breakdown of experience adjustments:					
gains/(losses) on plan assets <sup>(3)</sup>	(292)	255	553	(1,360)	(160)
gains/(losses) on obligations	26	(86)	(22)	34	25
Amount of obligations at the balance sheet date	10,945	9,988	9,300	8,110	8,820
Fair value of plan assets at the balance sheet date	6,045	5,712	4,920	3,998	5,413

<sup>(1)</sup> Of which a loss of 677 million recognized in equity in 2011 (loss of 316 million in 2010 and loss of 169 million in 2009 (see Note D.15.7.)) and loss of 4 million taken directly to the income statement in 2011 (losses of 44 million in 2010 and 38 million in 2009).

<sup>(2)</sup> Changes in assumptions relate mainly to changes in discount rates.

<sup>(3)</sup> Experience adjustments are due to trends in the financial markets.

The net pre-tax actuarial loss recognized directly in equity (excluding associates) was 2,145 million at December 31, 2011, versus 1,459 million at December 31, 2010 and 1,143 million at December 31, 2009.

As of December 31, 2011, the present value of obligations in respect of pensions and other long-term benefits under wholly or partially funded plans was 8,913 million, and the present value of unfunded obligations was 1,562 million (versus respectively 7,589 million and 1,969 million at December 31, 2010 and 6,897 million and 2,027 million at December 31, 2009).

In Germany, Sanofi is a member of a *Pensionskasse* multi-employer plan. This is a defined-benefit plan accounted for as a defined-contribution plan in accordance with the accounting policy described in Note B.23. Plan contributions cover the current level of annuities. However, the obligation arising from future increases in annuity rates is recognized as part of the overall pension obligation; it amounted to 489 million at December 31, 2011, versus 487 at December 31, 2010, and 449 million at December 31, 2009.

The table below shows the sensitivity of (i) the benefit cost recognized in the consolidated income statement, and (ii) the obligation in the consolidated balance sheet, to changes in healthcare costs associated with other post-employment benefits.

( million)	Sensitivity of assumptions 2011
1% increase in healthcare costs	
Impact on benefit cost for the period	3
Impact on obligation in the balance sheet	42
1% reduction in healthcare costs	

Impact on benefit cost for the period	(3)
Impact on obligation in the balance sheet	(33)

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The total cost of pensions and other benefits, which amounted to 320 million in 2011, is split as follows:

<i>( million)</i>	Year ended December 31, 2011	Year ended December 31, 2010 <sup>(1)</sup>	Year ended December 31, 2009 <sup>(1)</sup>
Cost of sales	117	121	111
Research and development expenses	81	98	98
Selling and general expenses	160	155	195
Other operating expenses	43	51	59
Financial expense <sup>(2)</sup>		9	13
Other gains and losses, and litigation <sup>(3)</sup>	(4)		
Restructuring costs	(77)	(73) <sup>(4)</sup>	77
<b>Total</b>	<b>320</b>	<b>361</b>	<b>553</b>

<sup>(1)</sup> Excluding Merial.

<sup>(2)</sup> This line comprises actuarial gains and losses on deferred compensation plans funded by assets recognized under the fair value option (see Note D.7.). These actuarial gains and losses are offset by changes in the fair value of those assets.

<sup>(3)</sup> Related to Dermik sale (see Note D.28.)

<sup>(4)</sup> Impact of plan curtailments following the redundancy programs announced in 2010 (see Note D.19.2.).

The timing of future estimated benefit payments on unfunded pensions and post employment benefits is as follows as of December 31, 2011:

<i>( million)</i>	Total	Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years
Estimated payments	1,453	64	121	140	1,128

The table below shows the expected cash outflows on pensions, other long-term and post employment benefits over the next ten years:

<i>( million)</i>	Pensions and other benefits
<b>Estimated employer's contribution in 2012</b>	<b>353</b>
<b>Estimated benefit payments:</b>	
2012	619
2013	618
2014	586
2015	607
2016	620
2017 to 2021	3,528

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.19.2. Restructuring provisions**

The table below shows movements in restructuring provisions classified in non-current liabilities and current liabilities:

<i>( million)</i>	December 31, 2011	December 31, 2010	December 31, 2009
<b>Balance, beginning of period</b>	<b>1,611</b>	<b>1,018</b>	<b>678</b>
of which:			
Classified in non-current liabilities	1,017	257	366
Classified in current liabilities	594	761	312
Change in provisions recognized in profit or loss for the period	861	1,073	837
Provisions utilized	(592)	(839)	(388)
Transfers	1	322 <sup>(1)</sup>	(110)
Unwinding of discount	38	27	3
Currency translation differences	11	10	(2)
<b>Balance, end of period</b>	<b>1,930</b>	<b>1,611</b>	<b>1,018</b>
of which:			
Classified in non-current liabilities	1,182	1,017	257
Classified in current liabilities	748	594	761

<sup>(1)</sup> Reclassification of social security charges and Fillon levies relating to early retirement plans in France (see Note D.19.1.).

Provision for employee termination benefits at December 31, 2011 amounted to 1,672 million, versus 1,265 million at December 31, 2010, mainly covering the redundancy programs announced as part of the adaptation of sales forces, R&D and industrial operations in France, the United States, and some other European countries. The provision relating to France ( 933 million at December 31, 2011 compared with 889 million at December 31, 2010) mainly represents the present value of gross annuities under early retirement plans not outsourced as of that date, plus social security charges and Fillon levies on those annuities and on outsourced annuities. The average residual period of carry under these plans was 3.3 years as of December 31, 2011 versus 3.6 years at December 31, 2010. In 2011, the premiums amount paid in connection with the outsourcing of annuities was 6 million versus 241 million at December 31, 2010.

The timing of future termination benefit payments is as follows:

<i>( million)</i>	Total	Year ended December 31, 2011 Benefit payments by period			
		Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years
Employee termination benefits					
France	933	189	231	339	174
Other countries	739	465	235	21	18
<b>Total</b>	<b>1,672</b>	<b>654</b>	<b>466</b>	<b>360</b>	<b>192</b>

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<i>( million)</i>	Year ended December 31, 2010				
	Benefit payments by period				
	Total	Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years
Employee termination benefits					
France	889	233	263	217	176
Other countries	376	226	127	13	10
<b>Total</b>	<b>1,265</b>	<b>459</b>	<b>390</b>	<b>230</b>	<b>186</b>

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Movements during 2011 recognized in profit or loss for the period mainly comprise expenses relating to measures taken to adapt sales and R&D functions in Western Europe and North America.

An analysis of restructuring costs by type is provided in Note D.27.

**D.19.3. Other provisions**

Other provisions include provisions for environmental, tax, commercial and product liability risks, and for litigation.

<i>( million)</i>	<b>December 31, 2011</b>	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Tax exposures	2,409	2,228	2,009
Environmental risks and remediation	764	781	695
Product liability risks, litigation and other	985	951	829
<b>Total</b>	<b>4,158</b>	<b>3,960</b>	<b>3,533</b>

Provisions for tax exposures are recorded if the Group is exposed to a probable risk resulting from a tax position adopted by the Group or a subsidiary, and the risk has been quantified at the balance sheet date.

Provisions for Environmental risks and remediation mainly relate to contingencies arising from business divestments. The movement during 2010 includes 105 million charged to restructuring costs in connection with the adaptation of chemical industrial facilities in France (see Note D.27.).

Identified environmental risks are covered by provisions estimated on the basis of the costs Sanofi believes it will be obliged to meet over a period not exceeding (other than in exceptional cases) 30 years. The Group expects that 126 million of these provisions will be utilized in 2012 and 293 million over the period from 2013 through 2016.

Product liability risks, litigation and other mainly comprises provisions for risks relating to product liability (including IBNR provisions as described in Note B.12.), government investigations, regulatory or competition law claims or contingencies arising from business divestments (other than environmental risks).

The main pending legal and arbitral proceedings and government investigations are described in Note D.22.

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A full risk and litigation assessment is performed with the assistance of the Group's legal advisers, and provisions are recorded as required by circumstances in accordance with the principles described in Note B.12.

### D.19.4. Other current liabilities

Other current liabilities break down as follows:

<i>( million)</i>	<b>December 31, 2011</b>	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Taxes payable	1,060	785	631
Employee-related liabilities	1,957	1,411	1,458
Restructuring provisions (see Note D.19.2.)	748	594	761
Interest rate derivatives (see Note D.20.)	27	3	62
Currency derivatives (see Note D.20.)	218	104	119
Amounts payable for acquisitions of non-current assets	191	267	251
Other liabilities	3,020	2,460	2,087
<b>Total</b>	<b>7,221</b>	<b>5,624</b>	<b>5,369</b>

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This item includes the current portion of provisions for litigation, sales returns and other risks; amounts due to associates and joint ventures (see Note D.6.) and amounts due to governmental agencies and the healthcare authorities (see Note D.23.).

**D.20. Derivative financial instruments and market risks**

The table below shows the fair value of derivative instruments as of December 31, 2011:

( million)	Non-current assets	Current assets	Total assets	Non- current liabilities	Current liabilities	Total liabilities	Fair value at	Fair value at	Fair value at
							Dec. 31 2011 (net)	Dec. 31, 2010 (net)	Dec. 31, 2009 (net)
<b>Currency derivatives</b>	<b>1</b>	<b>48</b>	<b>49</b>		<b>(218)</b>	<b>(218)</b>	<b>(169)</b>	<b>(104)</b>	<b>132</b>
<i>operational</i>	<i>1</i>	<i>12</i>	<i>13</i>		<i>(102)</i>	<i>(102)</i>	<i>(89)</i>	<i>(27)</i>	<i>(46)</i>
<i>financial</i>		<i>36</i>	<i>36</i>		<i>(116)</i>	<i>(116)</i>	<i>(80)</i>	<i>(77)</i>	<i>178</i>
<b>Interest rate derivatives</b>	<b>393</b>	<b>90</b>	<b>483</b>		<b>(27)</b>	<b>(27)</b>	<b>456</b>	<b>218</b>	<b>7</b>
<b>Total</b>	<b>394</b>	<b>138</b>	<b>532</b>		<b>(245)</b>	<b>(245)</b>	<b>287</b>	<b>114</b>	<b>139</b>

**Objectives of the use of derivative financial instruments**

Sanofi uses derivative instruments to manage operational exposure to movements in exchange rates, and financial exposure to movements in interest rates and exchange rates (where the debt is not contracted in the functional currency of the borrower or lender entity). Less frequently, Sanofi uses equity derivatives in connection with the management of its portfolio of equity investments.

Sanofi performs periodic reviews of its transactions and contractual agreements in order to identify any embedded derivatives, which are accounted for separately from the host contract in accordance with IAS 39. As of December 31, 2011, Sanofi had no material embedded derivatives.

**Counterparty risk**

As of December 31, 2011, all currency and interest rate hedges were contracted with leading banks, and no single counterparty accounted for more than 13% of the notional amount of the Group's overall currency and interest rate positions.

**a) Currency derivatives used to manage operational risk exposures**



Sanofi operates a foreign exchange risk hedging policy to reduce the exposure of operating income to fluctuations in foreign currencies, in particular the U.S. dollar. This policy involves regular assessments of the Group's worldwide foreign currency exposure, based on budget estimates of foreign-currency transactions to be carried out by the parent company and its subsidiaries. These transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of these transactions to exchange rate movements, Sanofi contracts economic hedges using liquid financial instruments such as forward purchases and sales of currency, and as applicable, call and put options, and combinations of currency options (collars).

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The table below shows operational currency hedging instruments in place as of December 31, 2011, with the notional amount translated into Euros at the relevant closing exchange rate:

As of December 31, 2011			Of which derivatives designated as cash flow hedges		Of which recognized in equity	Of which derivatives not eligible for hedge accounting	
	Notional amount	Fair value	Notional amount	Fair value		Notional amount	Fair value
( million)							
<b>Forward currency sales</b>	<b>3,446</b>	<b>(96)</b>				<b>3,446</b>	<b>(96)</b>
of which U.S. dollar	1,779	(59)				1,779	(59)
of which Japanese Yen	685	(22)				685	(22)
of which Russian ruble	310	(5)				310	(5)
of which Singapore dollar	71					71	
of which Australian dollar	63	(2)				63	(2)
<b>Forward currency purchases</b>	<b>1,077</b>	<b>7</b>				<b>1,077</b>	<b>7</b>
of which Singapore dollar	357	4				357	4
of which Swiss franc	165	2				165	2
of which Japanese Yen	124	3				124	3
of which Hungarian forint	107	(4)				107	(4)
of which U.S. dollar	69					69	
<b>Total</b>	<b>4,523</b>	<b>(89)</b>				<b>4,523</b>	<b>(89)</b>

As of December 31, 2011, none of these instruments had an expiry date after December 31, 2012, with the exception of a forward purchase of GBP40 million, expiring between 2012 and 2015.

These positions mainly hedge material future foreign-currency cash flows arising after the balance sheet date in relation to transactions carried out during the year ended December 31, 2011 and recognized in the balance sheet at that date. Gains and losses on these hedging instruments (forward contracts) are calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Consequently, the commercial foreign exchange result to be recognized on these items (hedges and hedged instruments) in 2012 is not expected to be material.

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The table below shows operational currency hedging instruments in place as of December 31, 2010, with the notional amount translated into Euros at the relevant closing exchange rate:

As of December 31, 2010			Of which derivatives designated as cash flow hedges		Of which recognized in equity	Of which derivatives not eligible for hedge accounting	
	Notional amount	Fair value	Notional amount	Fair value		Notional amount	Fair value
( million)							
<b>Forward currency sales</b>	<b>2,444</b>	<b>(25)</b>				<b>2,444</b>	<b>(25)</b>
of which U.S. dollar	1,380	(12)				1,380	(12)
of which Russian ruble	248	(7)				248	(7)
of which Japanese Yen	202	(4)				202	(4)
of which Pound sterling	95	2				95	2
of which Australian dollar	60	(1)				60	(1)
<b>Forward currency purchases</b>	<b>257</b>	<b>(2)</b>				<b>257</b>	<b>(2)</b>
of which Hungarian forint	84	(1)				84	(1)
of which U.S. dollar	51	(1)				51	(1)
of which Canadian dollar	31					31	
of which Russian ruble	30					30	
of which Japanese Yen	18					18	
<b>Total</b>	<b>2,701</b>	<b>(27)</b>				<b>2,701</b>	<b>(27)</b>

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The table below shows operational currency hedging instruments in place as of December 31, 2009, with the notional amount translated into euros at the relevant closing exchange rate.

As of December 31, 2009			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
( million)							
<b>Forward currency sales</b>	<b>2,800</b>	<b>(51)</b>	<b>583</b>	<b>(7)</b>	<b>(7)</b>	<b>2,217</b>	<b>(44)</b>
<i>of which U.S. dollar</i>	1,757	(41)	367	(5)	(5)	1,390	(36)
<i>of which Japanese yen</i>	269	1	150	(1)	(1)	119	2
<i>of which Russian ruble</i>	132	(4)				132	(4)
<i>of which Pound sterling</i>	111					111	
<i>of which Hungarian forint</i>	104	(1)				104	(1)
<b>Forward currency purchases</b>	<b>377</b>	<b>6</b>				<b>377</b>	<b>6</b>
<i>of which Hungarian forint</i>	114	3				114	3
<i>of which U.S. dollar</i>	69					69	
<i>of which Pound sterling</i>	68	1				68	1
<i>of which Canadian dollar</i>	42	1				42	1
<i>of which Swiss franc</i>	20					20	
<b>Put options purchased</b>	<b>448</b>	<b>14</b>	<b>20</b>	<b>1</b>		<b>428</b>	<b>13</b>
<i>of which U.S. dollar</i>	278	8				278	8
<b>Call options written</b>	<b>881</b>	<b>(17)</b>	<b>20</b>	<b>(1)</b>		<b>861</b>	<b>(16)</b>
<i>of which U.S. dollar</i>	555	(10)				555	(10)
<b>Put options written</b>	<b>278</b>	<b>(8)</b>				<b>278</b>	<b>(8)</b>
<i>of which U.S. dollar</i>	278	(8)				278	(8)
<b>Call options purchased</b>	<b>555</b>	<b>10</b>				<b>555</b>	<b>10</b>
<i>of which U.S. dollar</i>	555	10				555	10
<b>Total</b>	<b>5,339</b>	<b>(46)</b>	<b>623</b>	<b>(7)</b>	<b>(7)</b>	<b>4,716</b>	<b>(39)</b>

**b) Currency and interest rate derivatives used to manage financial risk exposures**

Cash pooling arrangements for foreign subsidiaries outside the euro zone, and some of the Group's financing activities, expose certain entities to financial foreign exchange risk. This is the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender. This risk is hedged by currency swaps or forward contracts, and mainly affects the Sanofi parent company.

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The table below shows operational currency hedging instruments in place as of December 31, 2011, with the notional amount translated into euros at the relevant closing exchange rate:

<i>( million)</i>	Notional amount	2011 Fair value	Expiry	Notional amount	2010 Fair value	Expiry	Notional amount	2009 Fair value	Expiry
<b>Forward currency purchases</b>	<b>2,719</b>	<b>24</b>		<b>2,086</b>	<b>(13)</b>		<b>6,760</b>	<b>185</b>	
<i>of which Pound sterling</i>	843	5	2012	565	(11)	2011	433	2	2010
<i>of which U.S. dollar</i>	828	10	2012	814	(8)	2011	5,634	180	2010
<i>of which Swiss franc</i>	274	1	2012	95	2	2011	152	1	2010
<b>Forward currency sales</b>	<b>4,900</b>	<b>(104)</b>		<b>2,728</b>	<b>(64)</b>		<b>3,169</b>	<b>(7)</b>	
<i>of which U.S. dollar</i>	2,964	(89)	2012	862	(26)	2012	1,634	(28)	2010
<i>of which Japanese yen</i>	993	(17)	2012	904	(24)	2011	837	18	2010
<i>of which Czech koruna</i>	251	4	2012	359	(7)	2011	394	7	2010
<b>Total</b>	<b>7,619</b>	<b>(80)</b>		<b>4,814</b>	<b>(77)</b>		<b>9,929</b>	<b>178</b>	

These forward contracts generate a net financial foreign exchange gain or loss arising from the interest rate gap between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency liabilities and receivables is offset by the change in the intrinsic value of the hedging instruments. In addition, the Group may hedge some future foreign-currency cash flows relating to investment or divestment transactions.

Following the financing of the Genzyme acquisition, the Group manages its net debt in two currencies, the euro and the U.S. dollar (see Note D.17.). The variable portion of this debt exposes the Group to an increase in interest rates, primarily on the one hand on the Eonia and Euribor and on the other hand on the U.S. Libor and Federal Fund Effective. In this context, in order to reduce the cost and/or volatility of its debt, we use interest rate swaps, cross-currency swaps, and interest rate options that alter the fixed/floating structure of our debt. Derivative instruments are partially denominated in euros and partially in U.S. dollars.

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These instruments were as follows as of December 31, 2011:

( million)	Notional amounts by expiry date as of December 31, 2011								Of which derivatives designated as cash flow hedges		Of which derivatives not eligible for hedge accounting Of which recognized in equity			
	2012	2013	2014	2015	2016	2019	2021	Total	Fair value	Notional	Fair value	Notional	Fair value	equity
<b>Caps</b>														
Purchases of Caps 0.50%	1,932							1,932	1			1,932	1	(1)
<b>Interest rate swaps</b>														
Pay floating / receive 2.73%					500			500	34	500	34			
Pay floating / receive 2.38%			1,200		1,000	800		3,000	204	3,000	204			
Pay floating / receive 1.86%							232	232	(1)	232	(1)			
Pay floating / receive 0.34%			386					386	1	386	1			
<b>Cross Currency Swaps</b>														
Pay floating /														
Receive JPY floating		92						92	58					
Pay 4.89% / receive CHF 3.26%	180							180	48			180	48	1
Pay 4.87% / receive CHF 3.38%				244				244	96			244	96	11
Pay floating /														
/ receive CHF 3.26%	167							167	42	167	42			
<b>Currency swaps hedging</b>														
<b>USD investments</b>														
Pay USD / receive	1,404							1,404	(27)					
<b>Total</b>	<b>3,683</b>	<b>92</b>	<b>1,586</b>	<b>244</b>	<b>1,500</b>	<b>800</b>	<b>232</b>	<b>8,137</b>	<b>456</b>	<b>4,285</b>	<b>280</b>	<b>2,356</b>	<b>145</b>	<b>11</b>

The table below shows instruments of this type in place as of December 31, 2010:

( million)	Notional amounts by expiry date as of December 31, 2010						Of which derivatives designated as fair value hedges		Of which derivatives designated as cash flow hedges Of which recognized in equity			
	2011	2012	2013	2015	2016	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	equity
<b>Interest rate swaps</b>												
Pay floating / receive 2.73%					500	500	12	500	12			
<b>Cross currency Swaps</b>												
Pay floating / receive JPY floating			92			92	47					
Pay 4.89% / receive CHF 3.26%		180				180	41			180	41	1
Pay 4.87% / receive CHF 3.38%				244		244	82			244	82	6

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Pay floating / receive CHF 3.26%	167					167	38	167	38			
<b>Currency swaps</b>												
pay / receive USD	489					489	(2)					
<b>Total</b>	<b>489</b>	<b>347</b>	<b>92</b>	<b>244</b>	<b>500</b>	<b>1,672</b>	<b>218</b>	<b>667</b>	<b>50</b>	<b>424</b>	<b>123</b>	<b>7</b>

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows instruments of this type in place as of December 31, 2009:

( million)	Notional amounts by expiry date as of December 31, 2009					Of which derivatives designated as fair value hedges			Of which derivatives designated as cash flow hedges Of which recognized in equity			
	2010	2012	2013	2015	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value		
<b>Interest rate swaps</b>												
Pay floating / receive 1.27%	1,000				1,000	2	1,000	2				
<b>Cross currency swaps</b>												
Pay floating / receive £ 5.50%	299				299	(62)	299	(62)				
Pay floating / receive JPY floating			92		92	21						
Pay floating / receive CHF 2.75%	122				122	16	122	16				
Pay 4.89% / receive CHF 3.26%		180			180	3			180	3	(2)	
Pay 4.87% / receive CHF 3.38%				244	244	23			244	23	(2)	
Pay floating / receive CHF 3.26%		167			167	4	167	4				
<b>Total</b>	<b>1,421</b>	<b>347</b>	<b>92</b>	<b>244</b>	<b>2,104</b>	<b>7</b>	<b>1,588</b>	<b>(40)</b>	<b>424</b>	<b>26</b>	<b>(4)</b>	

The change in the structure of the Group's debt arising from these financial instruments is described in Note D.17., which also includes an analysis of the Group's sensitivity to interest rates.

**D.21. Off balance sheet commitments****D.21.1. Off balance sheet commitments relating to operating activities**

The Group's off balance sheet commitments are analyzed as follows:

December 31, 2011 ( million)	Total	Payments due by period			
		Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
Operating lease obligations	1,456	284	406	245	521
Irrevocable purchase commitments <sup>(1)</sup>					
given	3,041	1,672	608	325	436
received	(247)	(105)	(76)	(42)	(24)
Research and development license agreements					
future service commitments <sup>(2)</sup>	944	196	307	416	25
potential milestone payments <sup>(3)</sup>	2,822	175	297	444	1,906
<b>Total</b>	<b>8,016</b>	<b>2,222</b>	<b>1,542</b>	<b>1,388</b>	<b>2,864</b>



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- (1) *These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3.) and (ii) goods and services. These irrevocable commitments as of December 31, 2010, amounted for given commitments to 2,658 million and (176) for received commitments.*
- (2) *Future service commitments relating to research and development license agreements mainly comprise research financing commitments, but also include consideration for access to technologies. Future service commitments as of December 31, 2010, amounted to 1,073 million.*
- (3) *This line includes all potential milestone payments on projects regarded as reasonably possible, i.e. on projects in the development phase. Payments contingent upon the attainment of sales targets once a product is on the market are excluded. Potential milestone payments as of December 31, 2010, amounted to 2,015 million.*

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**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Operating leases***

The Group leases certain of its properties and equipment used in the ordinary course of business under operating leases. Future minimum lease payments due under non-cancelable operating leases at December 31, 2011 amounted to 1,456 million (versus 1,291 million at December 31, 2010 and 1,197 million at December 31, 2009).

Total rental expense recognized in the year ended December 31, 2011 was 324 million (versus 281 million at December 31, 2010 and 279 million at December 31, 2009).

***Research and development license agreements***

In pursuance of its strategy, the Group may acquire technologies and rights to products. Such acquisitions may be made in various contractual forms: acquisitions of shares, loans, license agreements, joint development, and co-marketing. These contracts usually involve upfront payments on signature of the agreement, development milestone payments, and royalties. Some of these complex agreements include undertakings to finance research programs in future years and payments contingent upon specified development milestones, the granting of approvals or licenses, or the attainment of sales targets once a product is on the market.

The item Research and development license agreements comprises future service commitments to finance research and development or technology, and potential milestone payments regarded as reasonably possible (i.e. all potential milestone payments relating to projects in the development phase). This item excludes projects in the research phase ( 4.2 billion in 2011 and 4.1 billion in 2010) and payments contingent upon the attainment of sales targets once a product is on the market ( 4.4 billion in 2011 and 3.3 billion in 2010).

Potential milestone payments relating to development projects of the Pharmaceuticals segment amounted to 2.6 billion out of which 2.1 billion related to the main collaboration agreements described below.

In January 2008 Genzyme signed a collaboration agreement with Isis Pharmaceuticals S.A., which grants an exclusive license to develop and market Mipomersen, a lipopenic treatment in an advanced development phase for the treatment of severe familial hypercholesterolemia.

On May 13, 2011, Sanofi announced the signature of a license agreement with Glenmark Pharmaceuticals SA, a wholly-owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), for the development and commercialization of GBR500, a novel monoclonal antibody for the treatment of Crohn's Disease and other chronic autoimmune disorders.

In June 2010, Sanofi signed an exclusive global collaboration and license agreement with Ascenta Therapeutics, a U.S. biopharmaceutical company, on a number of molecules that could restore apoptosis (cell death) in tumor cells.

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At the end of April 2010, Sanofi signed a license agreement with Glenmark Pharmaceuticals S.A. (GPSA), a wholly-owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), for the development and commercialization of novel agents to treat chronic pain. Those agents are vanilloid receptor (TRPV3) antagonist molecules, including a first-in-class clinical compound, GRC 15300, which is currently in Phase I clinical development.

In April 2010, Sanofi signed a global license agreement with CureDM Group Holdings, LLC (CureDM) for Pancreate™, a novel human peptide which could restore a patient's ability to produce insulin and other pancreatic hormones in both type 1 and type 2 diabetes.

In December 2009, Sanofi and the U.S. biotechnology company Alopexx Pharmaceuticals (LLC) simultaneously signed (i) a collaboration agreement, and (ii) an option for a license on an antibody for the prevention and treatment of infections originating in the bacterium that causes plague and other serious infections.

End September 2009, Sanofi and Merrimack Pharmaceuticals Inc. signed an exclusive global licensing and collaboration agreement covering the MM-121 molecule for the management of solid malignancies.

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In May 2009, Sanofi signed a global license agreement with Exelixis, Inc. for XL147 and XL765, and simultaneously signed an exclusive research collaboration agreement for the discovery of inhibitors of Phosphoinositide-3-Kinase (PI3K) for the management of malignant tumors. On December 22, 2011, Sanofi and Exelixis, Inc. agreed to end their collaboration for discovery of inhibitors of Phosphoinositide-3-Kinase (PI3K) for the management of malignant tumors.

In May 2009, Sanofi signed a collaboration and licensing agreement with Kyowa Hakko Kirin Co., Ltd., under which Sanofi obtained the worldwide rights to the anti-LIGHT fully human monoclonal antibody. This anti-LIGHT antibody is presently at preclinical development stage, and is expected to be first-in-class in the treatment of ulcerative colitis and Crohn's disease.

In September 2003, Sanofi signed a collaboration agreement in oncology with Regeneron Pharmaceuticals, Inc. (Regeneron) to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Sanofi will pay 100% of the development costs of the VEGF Trap. Once a VEGF Trap product starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by Sanofi) in accordance with a formula based on Regeneron's share of the profits.

In November 2007, Sanofi signed a collaboration agreement with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies. This agreement was broadened, and its term extended, on November 10, 2009. Under the terms of the development agreement, Sanofi committed to fund 100% of the development costs of Regeneron's antibody research program until 2017. Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) half of the development costs borne by Sanofi.

Sanofi has also entered into the following major agreements, which are currently in a less advanced research phase:

On June 28, 2011, Sanofi announced the signature of an exclusive worldwide research collaboration agreement and option for license with Rib-X Pharmaceuticals, Inc. for novel classes of antibiotics resulting from Rib-X's RX-04 program for the treatment of resistant Gram-positive and resistant Gram-negative pathogens.

December 2010: a global licensing and patent transfer agreement with Ascendis Pharma (Ascendis) on the proprietary Transcon Linker and Hydrogel Carrier technology developed by Ascendis for precise, time-controlled release of therapeutic active ingredients into the body. The agreement will enable Sanofi to develop, manufacture and commercialize products combining this technology with active molecules for the treatment of diabetes and related disorders.

December 2010: alliance with Avila Therapeutics<sup>TM</sup> Inc. (Avila) to discover target covalent drugs for the treatment of cancers, directed towards six signaling proteins that are critical in tumor cells. Under the terms of the agreement, Sanofi will have access to Avila's proprietary Avilomic<sup>SM</sup> platform offering protein silencing for these pathogenic proteins.

December 2010: an exclusive global licensing option with Oxford BioTherapeutics for three existing antibodies, plus a research and collaboration agreement to discover and validate new targets in oncology.

September 2010: alliance with the Belfer Institute of Applied Cancer Science at the Dana-Farber Cancer Institute (DFCI) to identify novel targets in oncology for the development of new therapeutic agents directed towards these targets and their associated biomarkers. Under the terms of the agreement, Sanofi will have access to the Belfer Institute's anticancer target identification and validation platform and to its translational medicine resources. Sanofi also has an option over an exclusive license to develop,

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manufacture and commercialize novel molecules directed towards the targets identified and validated under this research collaboration.

June 2010: alliance with Regulus Therapeutics Inc. to discover, develop and commercialize novel micro-RNA therapeutics, initially in fibrosis. Sanofi also received an option, which if exercised, would provide access to the technology to develop and commercialize other micro-RNA based therapeutics, beyond the first four targets.

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October 2009: agreement with Micromet, Inc. to develop a BiTE<sup>®</sup> antibody against a tumor antigen present at the surface of carcinoma cells.

Sanofi Pasteur has entered into a number of collaboration agreements. Milestone payments relating to development projects under those agreements amounted to 0.2 billion in 2011.

In December 2009, Sanofi Pasteur signed a donation letter to the World Health Organization (WHO). The terms of the agreement committed Sanofi Pasteur to donate 10% of its future output of vaccines against A(H1N1), A(H5N1) or any other influenza strain with pandemic potential, up to a maximum of 100 million doses. Since this agreement was put in place, Sanofi Pasteur has already donated to the WHO some of the doses covered by the commitment.

**D.21.2. Off balance sheet commitments related to the financing of the Group*****Credit facilities***

The undrawn credit facilities break down as follows:

December 31, 2011	Total	Payments due by period			
		Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
( million)					
General-purpose facilities	10,046	3,046		7,000	

As of December 31, 2010, credit facilities including Genzyme acquisition facilities amounted to 23,464 million.

***Guarantees***

Guarantees given and received (mainly surety bonds) are as follows:

( million)	2011	2010	2009
Guarantees given	3,296	2,558	2,358
Guarantees received	(751)	(185)	(171)

**D.21.3. Off balance sheet commitments relating to the scope of consolidation**

The maximum amount of contingent consideration related to business combinations is presented in Note D.18.

**D.22. Legal and Arbitral Proceedings**

Sanofi and its affiliates are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. Provisions related to legal and arbitral proceedings are recorded in accordance with the principles described in Note B.12.

Most of the issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain. Contingent liabilities are cases for which either we are unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable. In either case, a brief description of the nature of the contingent liability is disclosed and, where practicable, an estimate of its financial effect, an indication of the uncertainties relating to the amount and timing of any outflow, and the possibility of any reimbursement are provided in application of paragraph 86 of IAS 37.

In the cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed, we have indicated our losses or the amount of provision accrued that is the estimate of the probable loss.

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In a limited number of ongoing cases, while we are able to make a reasonable estimate of the expected loss or range of the possible loss and have accrued a provision for such loss, we believe that publication of this information on a case-by-case basis or by class would seriously prejudice the Company's position in the ongoing legal proceedings or in any related settlement discussions. Accordingly, in those cases, we have disclosed information with respect to the nature of the contingency but have not disclosed our estimate of the range of potential loss, in accordance with paragraph 92 of IAS 37.

These assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Our assessments are based on estimates and assumptions that have been deemed reasonable by management. We believe that the aggregate provisions recorded for the above matters are adequate based upon currently available information. However, given the inherent uncertainties related to these cases and involved in estimating contingent liabilities, we could in the future incur judgments that could have a material adverse effect on our net income in any particular period.

Long term provisions other than provisions for pensions and other benefits and restructuring provisions are disclosed in Note D.19.3.

Provisions for product liability risks, litigation and other amount to 985 million in 2011. These provisions are mainly related to product liabilities, government investigations, competition law, regulatory claims, warranties in connection with certain contingent liabilities arising from business divestitures other than environmental matters and other claims.

Provisions for environmental risks and remediation amount to 764 million in 2011, the majority of which are related to contingencies that have arisen from business divestitures.

**a) Products***Sanofi Pasteur Hepatitis B Vaccine Product Litigation*

Since 1996, more than 180 lawsuits have been filed in various French civil courts against Sanofi Pasteur SA and/or Sanofi Pasteur MSD S.N.C., the former a French subsidiary of Sanofi, and the latter a joint venture company with Merck & Co., Inc. In such lawsuits, the plaintiffs allege that they suffer from a variety of neurological disorders and autoimmune diseases, including multiple sclerosis and Guillain-Barré syndrome as a result of receiving the hepatitis B vaccine. The French Supreme Court (*Cour de Cassation*), in July 2009, upheld a decision of the Court of Appeals of Lyon ordering Sanofi Pasteur MSD S.N.C. to pay damages of 120,000 to a claimant whose multiple sclerosis appeared shortly after her vaccination against the hepatitis B virus; however, in several cases before and after the July 2009 decision, the *Cour de Cassation* upheld several decisions of various Courts of Appeals (including the Court of Appeals of Paris), rejecting claims alleging such causal link. Nevertheless, it is difficult to provide an opinion on the evolution and final outcome of these cases. A number of claims remain to be adjudicated and there can be no assurance that cases decided to date will be representative of future decisions and that additional claims will not be filed in France or other countries.

In January 2008, both the legal entity Sanofi Pasteur MSD S.N.C., and a corporate officer of this company, as well as a former corporate officer of Sanofi Pasteur S.A., were placed under investigation in an ongoing criminal inquiry in France relating to alleged side effects caused by the



hepatitis B vaccine.

*Plavix® Product Litigation*

Over 250 lawsuits have been filed against affiliates of the Group and Bristol-Myers Squibb seeking recovery under state law for personal injuries allegedly sustained in connection with the use of Plavix®. The actions are venued in several jurisdictions, including the federal and/or state courts of New Jersey, New York, and Illinois. Defendants filed an application before the Judicial Panel on Multidistrict Litigation (JPML) for coordinated proceedings and seeking the transfer of current and future federal cases to the U.S. District Court for the District of New Jersey. The application was denied. A tolling agreement (agreement which tolls or suspends the running of the statute of limitations) remains in effect for additional potential plaintiffs. At this stage of the litigation, a reasonable estimate of the financial effect of these cases is not practicable.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****b) Patents***Ramipril Canada Patent Litigation*

Sanofi is involved in a number of legal proceedings involving companies which market generic Altace® (ramipril) in Canada. Notwithstanding proceedings initiated by Sanofi, the following eight manufacturers: Apotex (in 2006), Teva (formerly Novopharm), Sandoz and Cobalt (in 2007), and Riva, Genpharm, Ranbaxy and Pro Doc (in 2008), obtained marketing authorizations from the Canadian Minister of Health for generic versions of ramipril in Canada. Following the marketing of these products, Sanofi filed patent infringement actions against all eight companies. In the patent infringement actions against Apotex and Teva, the Federal Court of Canada ruled on June 29, 2009 that the asserted patent was invalid. Each of Teva, Apotex and Riva initiated Section 8 damages claims against Sanofi, seeking compensation for their alleged inability to market a generic ramipril during the time taken to resolve the proceedings against the Canadian Ministry of Health. The Apotex and Teva trials have been scheduled for the first quarter of 2012, while the Riva trial has been scheduled for the third quarter of 2012. Sanofi's appeals of the Federal Court of Canada decisions on the patent invalidity was dismissed by the Federal Court of Appeal on November 2, 2011 and Sanofi has sought leave to appeal to the Supreme Court. Neither appeal suspends the advancement of the existing damages claims.

**c) Government Investigations, Competition Law and Regulatory Claims***Civil Suits Pricing and Marketing Practices*

*Average Wholesale Prices (AWP) Class Actions.* Aventis Pharmaceuticals Inc. (API) is a defendant in several U.S. lawsuits seeking damages on behalf of multiple putative classes of individuals and entities that allegedly overpaid for certain pharmaceuticals as a result of the AWP pricing which were used to set Medicare and Medicaid reimbursement levels. Aventis Behring and Sanofi-Synthélabo Inc. were also defendants in some of these cases. These suits allege violations of various statutes, including state unfair trade, unfair competition, consumer protection and false claim statutes.

A group of eleven defendants, including Sanofi defendants, reached a tentative global settlement of the claims of the insurers and consumers, for a total of U.S.\$125 million. The defendants' respective shares of the settlement amount are confidential. This settlement was granted preliminary approval by the U.S. District Court in Boston in early July 2008. In December 2011, the Court granted the settlement final approval. Once any objections are resolved, this will resolve all class action suits of the U.S. District Court in Boston. Sanofi's share of the global settlement is fully covered by existing reserves.

*§340B Suit.* On August 18, 2005, the County of Santa Clara, California filed a suit against Aventis Pharmaceuticals Inc. and fourteen other pharmaceutical companies originally in the Superior Court of the State of California, County of Alameda, alleging that the defendants had overcharged Public Health Service entities for their pharmaceutical products in breach of pharmaceutical pricing agreements between the defendants and the Secretary of Health and Human Services. Subsequently, the case was removed to the U.S. District for the Northern District of California. In May 2009, the Court denied the plaintiffs' motion for class certification without prejudice. All proceedings in the District Court were stayed pending the decision of the Supreme Court concerning whether plaintiffs have a private right of action. On March 29, 2011, the U.S. Supreme Court issued an opinion concluding that plaintiffs do not have a private right of action, ruling in favor of Aventis Pharmaceuticals and

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fourteen other defendants, and restoring an order of dismissal that previously had been entered by the U.S. District Court for the Northern District of California. Accordingly, the District Court is expected to receive, in due course, a mandate ordering it to dismiss this case.

### *Cipro® Antitrust Litigation*

Since August 2000, Aventis Pharmaceuticals Inc. (API) has been a defendant in several related cases in U.S. state and federal courts alleging that API and certain other pharmaceutical manufacturers violated U.S. antitrust laws and various state laws by settling a patent dispute regarding the brand-name prescription drug Cipro® in a manner which allegedly delayed the arrival of generic competition. In March 2005, the U.S. District Court for the

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Eastern District of New York granted Sanofi's summary judgment motions, and issued a judgment in favor of API and the other defendants in this litigation. By Order entered October 15, 2008, the U.S. Court of Appeals for the Federal Circuit affirmed the District Court's ruling in the appeal by indirect purchaser plaintiffs; the direct purchaser plaintiffs' appeal was heard by the U.S. Court of Appeals for the Second Circuit in April 2009. On April 29, 2010, the Federal Circuit affirmed the District Court's ruling dismissing the direct purchasers' case on summary judgment. The direct purchaser plaintiffs requested a rehearing en banc, which was denied by the Federal Circuit in September 2010. Following an appeal to the U.S. Supreme Court by the direct purchaser plaintiffs, on March 7, 2011, the U.S. Supreme Court denied the direct purchaser plaintiff's petition for a writ of certiorari, thus ending the federal litigation relating to Cipr®.

*DDAVP® Antitrust Litigation*

Subsequent to the decision of the U.S. District Court for the Southern District of New York in February 2005 holding the patent rights at issue in the DDAVP® tablet litigation to be unenforceable as a result of inequitable conduct, eight putative class actions have been filed claiming injury as a result of Ferring B.V. and Aventis Pharmaceuticals Inc.'s alleged scheme to monopolize the market for DDAVP® tablets in violation of the Sherman Act and the antitrust and deceptive trade practices statutes of several states. On November 6, 2006, the District Court dismissed these claims. Oral argument on plaintiffs' appeal of the decision to dismiss was heard by the U.S. Court of Appeals for the Second Circuit in 2008. By Order dated October 16, 2009, the appellate court reversed and remanded the case back to the District Court. Petitions for rehearing and rehearing en banc were denied. In August 2011, Aventis Pharmaceuticals and Ferring reached an agreement with direct purchaser plaintiffs resolving their claims. Aventis Pharmaceuticals agreed to resolve these claims for U.S.\$3.5 million.

*Plavix® Antitrust Claim*

On March 23, 2006, the U.S. retailer, The Kroger Co., filed an antitrust complaint in the District Court for the Southern District of Ohio against Sanofi, Bristol-Myers Squibb Co. and Apotex Corp. alleging antitrust violations by the defendants in relation to their tentative agreement to settle the U.S. Plavix® patent litigation (see Item 8 Patents Apotex Settlement Claim above). Seventeen other complaints have since been filed by direct and indirect purchasers of Plavix® on the same or similar grounds. Plaintiffs seek relief including injunctive relief and monetary damages. Defendants have moved to dismiss the consolidated direct and indirect purchasers' complaints. Following Orders entered by the U.S. District Court for the Southern District of Ohio in October 2009, and in January 2011, dismissing the claims of the direct purchasers and indirect purchasers respectively, Plaintiffs have not appealed, thus ending these matters.

*Lovenox® Antitrust Litigation*

In August 2008, Eisai Inc. (Eisai) brought suit against Sanofi U.S. LLC and Sanofi U.S. Inc. in the U.S. District Court for the District of New Jersey alleging that certain contracting practices for Lovenox® violate federal and state antitrust laws. The proceedings are in the discovery phase. An estimate of the financial effect of this case is not practicable at this stage of the litigation.

**d) Other litigation and arbitration**

*Hoechst Shareholder Litigation*

On December 21, 2004, the extraordinary general meeting of Sanofi's German subsidiary Hoechst AG (now Hoechst GmbH) approved a resolution transferring the shares held by minority shareholders to Sanofi for compensation of €56.50 per share. Certain minority shareholders filed claims contesting the validity of the resolution, preventing its registration with the commercial register of Frankfurt and its entry into effect.

On July 12, 2005, this litigation was settled. As a consequence, the squeeze out has been registered in the commercial register making Sanofi the sole shareholder of Hoechst AG.

According to the settlement agreement, the cash compensation has been increased to €63.80 per share. The cash compensation was further increased by another €1.20 per share for those outstanding shareholders who *inter*

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*alia* waived in advance any increase of the cash compensation obtained through a judicial appraisal proceeding (*Spruchverfahren*) brought by former minority shareholders. Minority shareholders representing approximately 5 million shares did not accept such offer. Subsequently, a number of former minority shareholders of Hoechst initiated a judicial appraisal proceeding with the District Court of Frankfurt (*Landgericht Frankfurt am Main*) contesting the amount of the cash compensation paid in the squeeze out. In its decision dated January 27, 2012, the District Court of Frankfurt ruled in favor of Sanofi, confirming the amount of 63.80 per share as adequate cash compensation. Plaintiffs may appeal.

*Zimulti® /Acomplia® (rimonabant) Class Action*

In November 2007, a purported class action was filed in the U.S. District Court for the Southern District of New York on behalf of purchasers of Sanofi shares. The complaint charged Sanofi and certain of its current and former officers and directors with violations of the Securities Exchange Act of 1934. The complaint alleged that defendants' statements regarding rimonabant (a product withdrawn from the market, formerly registered and marketed under the trademark Acomplia® in Europe and Zimulti® in the US) were materially false and misleading when made because defendants allegedly concealed data concerning certain alleged secondary effects of rimonabant, in particular, suicidality in patients suffering from depression. In September 2009, the motion was dismissed with prejudice. The plaintiffs filed a motion for reconsideration. On July 27, 2010, the U.S. District Court for the Southern District of New York granted plaintiff's motion to reconsider and authorized plaintiffs to submit an amended complaint. In November 2010, the District Court heard arguments on Sanofi's motion to dismiss plaintiff's amended complaint. By Order dated March 31, 2011, the U.S. District Court for the Southern District of New York dismissed a number of individual defendants, however, denied Sanofi's request to dismiss the company, as well as one of its current officers and one of its former officers. On November 11, 2011, Plaintiffs filed a motion for class certification. A reliable measure of potential liabilities arising from this purported class action is not possible at this stage of the litigation.

*Merial Heartgard® Advertisement Claim*

On August 31, 2009, a purported class action lawsuit was filed against Merial, alleging that Merial engaged in false and misleading advertising of Heartgard® and Heartgard® Plus by claiming 100% efficacy in the prevention of heartworm disease, as well as the prevention of zoonotic diseases. Plaintiffs also request punitive damages and a permanent injunction with respect to the alleged advertising. The proceedings are ongoing and the class has not been certified yet. A reliable measure of potential liabilities arising from this putative class action is not possible at this stage of the litigation.

*Merial Frontline® Advertisement Claim*

From October 2011 through January 2012, ten putative class actions were filed against Merial in various U.S. federal courts, each alleging that the plaintiffs sustained damages after purchasing defendants' products (Merial's Frontline® and/or Certifect® brands and Bayer's Advantag® and Advantix® brands) for their pets' flea problems. These actions have been transferred to the U.S. District Court for the Northern District of Ohio for coordinated proceedings in multi-district litigation.

The complaints seek injunctive relief and contain counts for violations of consumer protection or deceptive trade practices acts, false advertising, breach of implied and express warranty and violations of the Magnuson-Moss Warranty Act. Four of the complaints seek U.S.\$32 billion in

damages, two complaints seek greater than U.S.\$4 billion in damages, and the remaining four complaints seek damages in excess of U.S.\$5 million, which is merely the jurisdictional threshold. The proceedings are ongoing and no class has been certified. A reliable measure of potential liabilities arising from this putative class action litigation is currently not possible.

**e) Contingencies arising from certain Business Divestitures**

Sanofi and its subsidiaries, Hoechst and Aventis Agriculture, divested a variety of mostly chemical, including agro-chemical, businesses as well as certain health product businesses in previous years. As a result of these divestitures, the Group is subject to a number of ongoing contractual and legal obligations regarding the state of the sold businesses, their assets, and their liabilities.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Aventis Behring Retained Liabilities*

The divestment of Aventis Behring and related protein therapies assets became effective on March 31, 2004. The purchase agreement contained customary representations and warranties running from Sanofi as seller to CSL Limited as purchaser. Sanofi has indemnification obligations that generally expired on March 31, 2006 (the second anniversary of the closing date). However, some indemnification obligations, having a longer duration, remain in effect, for example, indemnification obligations relating to the due organization, capital stock and ownership of Aventis Behring Companies runs through March 31, 2014, and product liability indemnification through March 31, 2019, subject to an extension for claims related to certain types of product liability notified before such date. Furthermore, for tax-related issues, the indemnification obligation of Sanofi covers all taxable periods that end on or before the closing date and expires thirty days after the expiration of the applicable statute of limitations. In addition, the indemnification obligations relating to certain specified liabilities, including HIV liability, survive indefinitely.

Under the indemnification agreement, Sanofi is generally obligated to indemnify, only to the extent indemnifiable, losses exceeding U.S.\$10 million and up to a maximum aggregate amount of U.S.\$300 million. For environmental claims, the indemnification due by Sanofi equals 90% of the indemnifiable losses. Product liability claims are generally treated separately, and the aggregate indemnification is capped at U.S.\$500 million. Certain indemnification obligations, including those related to HIV liability, as well as tax claims, are not capped in amount.

*Aventis CropScience Retained Liabilities*

The sale by Aventis Agriculture S.A. and Hoechst GmbH (both legacy companies of Sanofi) of their aggregate 76% participation in Aventis CropScience Holding (ACS) to Bayer and Bayer CropScience AG (BCS), the wholly owned subsidiary of Bayer which holds the ACS shares, was effective on June 3, 2002. The stock purchase agreement dated October 2, 2001, contained customary representations and warranties with respect to the sold business, as well as a number of indemnifications, in particular with respect to: environmental liabilities (the representations and warranties and the environmental indemnification are subject to a cap of \$836 million, except for certain legal representations and warranties and specific environmental liabilities, notably third-party site claims such as (i) the natural resources damages (NRD) claim filed by the state of New Jersey against BCS in 2007 in relation to the Factory Lane site, and (ii) a remediation and NRD project underway in Portland, Oregon); taxes; certain legal proceedings; claims related to StarLink® corn; and certain pre-closing liabilities, in particular, product liability cases (which are subject to a cap of \$418 million). There are various periods of limitation depending upon the nature or subject of the indemnification claim. Further, Bayer and BCS are subject to a number of obligations regarding mitigation and cooperation.

Starting with a first settlement agreement signed in December 2005, Aventis Agriculture and Hoechst have resolved a substantial number of disputes with Bayer and BCS AG, including the termination of arbitration proceedings initiated in August 2003 for an alleged breach of a financial statement-related representation contained in the stock purchase agreement, and numerous other warranty and indemnification claims asserted under the stock purchase agreement, including claims relating to certain environmental and product liabilities. A number of other outstanding claims remain unresolved.

*LLRICE601 and LLRICE604 U.S. Litigation:* BCS has sent Sanofi notice of potential claims for indemnification under various provisions of the stock purchase agreement. These potential claims relate to several hundred individual complaints that have been filed since August 2006 by rice growers, millers, and distributors in U.S. state and federal courts against a number of current and former subsidiaries (collectively the CropScience Companies ) which were part of the ACS group prior to Bayer's acquisition of the ACS shares. Plaintiffs in these cases seek to recover damages in connection with the detection of trace amounts of the genetically modified rice called Liberty Link® Rice 601 (also known as



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LLRICE601 ) or Liberty<sup>®</sup> Rice 604 (also known as LLRICE604 ) in samples of commercial long-grain rice. LLRICE601 and LLRICE604, each a variety of long grain rice genetically altered to resist Liberty<sup>®</sup> Herbicide, were grown in field tests in the United States from the years 1998 to 2001. Plaintiffs assert a number of causes of action, alleging that the CropScience Companies failed to take adequate measures to prevent cross-pollination or commingling of LLRICE601 and/or LLRICE604 with conventional rice.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In July 2011, BCS reached settlement agreements with attorneys representing U.S. long-grain rice growers at a total amount of U.S.\$750 million, thus settling cases that were part of the U.S. federal multi-district litigation, as well as those cases before state courts. The settlement agreement with state court grower plaintiffs does not include certain cases which reached verdicts in Arkansas State Court, where the court has awarded plaintiffs in such cases a collective total of approximately U.S.\$54 million in compensatory and punitive damages. With respect to one of those cases, the Arkansas Supreme Court upheld the state court jury award of U.S.\$42 million in punitive damages, ruling that the statutory cap on punitive damages is unconstitutional. BCS has reached settlement with a number of non-grower plaintiffs, primarily millers and European importers, for a total of approximately U.S.\$80 million. In March 2011, an Arkansas State Court jury awarded Riceland Foods U.S.\$11.8 million in compensatory damages and U.S.\$125 million in punitive damages. In June 2011 (prior to the above-mentioned Arkansas Supreme Court decision) punitive damages were reduced to U.S.\$1 million in application of the statutory cap. Both BCS and Riceland have appealed the decision. Non-grower cases are scheduled for trial through 2012.

Sanofi denies direct or indirect liability for these cases, and has so notified BCS.

In a related development, the FDA has concluded that the presence of LLRICE601 in the food and feed supply poses no safety concerns and, on November 24, 2006, the United States Department of Agriculture (USDA) announced it would deregulate LLRICE601. With respect to LLRICE 604, the USDA announced, in March 2007, that the PAT protein contained in LLRICE604 has a long history of safe use and is present in many deregulated products. Further to an investigation regarding the causation chain that led to contamination, in October 2007, the USDA declined to pursue enforcement against BCS.

*Aventis Animal Nutrition Retained Liabilities*

Aventis Animal Nutrition S.A. and Aventis (both legacy companies of Sanofi) signed an agreement for the sale to Drakkar Holdings S.A. of the Aventis Animal Nutrition business effective in April 2002. The sale agreement contained customary representations and warranties. Sanofi's indemnification obligations ran through April 2004, except for environmental indemnification obligations (which run through April 2012), tax indemnification obligations (which run through the expiration of the applicable statutory limitation period), and antitrust indemnification obligations (which extend indefinitely). The indemnification undertakings are subject to an overall cap of 223 million, with a lower cap for certain environmental claims. Indemnification obligations for antitrust and tax claims are not capped.

*Celanese AG Retained Liabilities*

The demerger of the specialty chemicals business to Celanese AG (now trading as Celanese GmbH) became effective on October 22, 1999. Under the demerger agreement between Hoechst and Celanese, Hoechst expressly excluded any representations and warranties regarding the shares and assets demerged to Celanese. However, the following obligations of Hoechst are ongoing:

While all obligations of Hoechst (i) resulting from public law or (ii) pursuant to current or future environmental laws or (iii) vis-à-vis third parties pursuant to private or public law related to contamination (as defined) have been transferred to Celanese in full, Hoechst splits with Celanese any such cost incurred under these obligations applying a 2:1 ratio. The liability for indemnification of Hoechst under the demerger agreement is with Celanese and an affiliate.

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To the extent Hoechst is liable to purchasers of certain of its divested businesses (as listed in the demerger agreement), Celanese and an affiliate are liable to indemnify Hoechst, as far as environmental damages are concerned, for aggregate liabilities up to 250 million, liabilities exceeding such amount will be borne by Hoechst alone up to 750 million, and amounts exceeding 750 million will be borne 2/3 by Hoechst and 1/3 by Celanese without any further caps.

Compensation paid to third parties by Celanese through December 31, 2011, was significantly below the first threshold of 250 million.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Rhodia Retained Liabilities*

In connection with the initial public offering of Rhodia in 1998, Rhône-Poulenc (later named Aventis, to which Sanofi is the legal successor in interest) entered into an environmental indemnification agreement with Rhodia on May 26, 1998 under which, subject to certain conditions, Rhodia was entitled to claim indemnification from Aventis with respect to direct losses resulting from third-party claims or public authority injunctions for environmental damages. Aventis and Rhodia entered into a settlement agreement on March 27, 2003 under the terms of which the parties settled all environmental claims in connection with the environmental indemnification agreement. Notwithstanding this settlement agreement, Rhodia and certain of its subsidiaries have unsuccessfully sought indemnification for environmental costs in the United States and Brazil. In both instances, the suits were decided in favor of Sanofi, with the court holding that the settlement precluded the indemnification claims. The decision in Brazil was under appeal by Rhodia. On September 6, 2011, the Court of Appeals rendered a decision favorable to Sanofi, confirming that the Environmental Settlement concluded in March 2003 precludes any claim from Rhodia in these matters. Rhodia may appeal to the Supreme Court in Brazil.

On April 13, 2005, Rhodia initiated an *ad hoc* arbitration procedure seeking indemnification from Sanofi for the financial consequences of the environmental liabilities and pension obligations that were allocated to Rhodia through the various operations leading to the formation of Rhodia in 1997, amounting respectively to 125 million and 531 million. Rhodia additionally sought indemnification for future costs related to transferred environmental liabilities and coverage of all costs necessary to fully fund the transfer of pension liabilities out of Rhodia's accounts. The arbitral tribunal determined that it has no jurisdiction to rule on pension claims and that Rhodia's environmental claims are without merit. In May 2008, the Paris Court of Appeals rejected the action initiated by Rhodia to nullify the 2006 arbitral award in favor of Sanofi.

On July 10, 2007, Sanofi was served with a civil suit brought by Rhodia before the Commercial Court of Paris (*Tribunal de Commerce de Paris*) seeking indemnification on the same grounds as described above. The allegations before the Commercial Court of Paris are comparable to those asserted in Rhodia's arbitration demand. On February 10, 2010, Rhodia submitted its pleadings brief (*conclusions récapitulatives*) in which it has asked the Court to hold that Sanofi was at fault in failing to provide Rhodia with sufficient capital to meet its pension obligations and environmental liabilities, and has claimed indemnification in the amount of 1.3 billion for retirement commitments and approximately 311 million for environmental liabilities. On December 14, 2011, the Commercial Court ruled in favor of Sanofi, rejecting all of Rhodia's allegations and claims. Rhodia has appealed this decision.

*Rhodia Shareholder Litigation*

In January 2004, two minority shareholders of Rhodia and their respective investment vehicles filed two claims before the Commercial Court of Paris (*Tribunal de Commerce de Paris*) against Aventis, to which Sanofi is successor in interest, together with other defendants including former directors and statutory auditors of Rhodia from the time of the alleged events. The claimants seek a judgment holding the defendants collectively liable for alleged management errors and for alleged publication of misstatements between 1999 and 2002, and *inter alia* regarding Rhodia's acquisition of the companies Albright & Wilson and ChiRex. These shareholders seek a finding of joint and several liability for damages to be awarded to Rhodia in an amount of 925 million for alleged harm to the Company (a derivative action), as well as personal claims of 4.3 million and 125.4 million for their own alleged individual losses. Sanofi contests both the substance and the admissibility of these claims.

Sanofi is also aware of three criminal complaints filed in France by the same plaintiffs and of a criminal investigation order issued by the Paris public prosecutor following the submission of the report issued by the *Autorité des Marchés Financiers* regarding Rhodia's financial

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communications. In 2006, the Commercial Court of Paris accepted Sanofi and the other defendants' motion to stay the civil litigation pending the conclusion of the criminal proceedings. The plaintiffs' appeals against this decision, first before the Court of Appeals, and then before the French Supreme Court (*Cour de Cassation*), were both rejected.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Clariant Retained Liabilities - Specialty Chemicals Business*

Hoechst conveyed its specialty chemicals business to Clariant AG (Clariant) pursuant to a 1997 agreement. While Clariant has undertaken to indemnify Hoechst for all costs incurred for environmental matters relating to purchased sites, certain ongoing indemnification obligations of Hoechst for environmental matters in favor of Clariant can be summarized as follows:

Costs for environmental matters at the sites taken over, directly or indirectly, by Clariant and not attributable to a specific activity of Hoechst or of a third party not related to the business transferred to Clariant are to be borne by Clariant to the extent the accumulated costs since the closing in any year do not exceed a threshold amount for the then-current year. The threshold increases annually from approximately 102 million in 1997/98 to approximately 816 million in the fifteenth year after the closing. Only the amount by which Clariant's accumulated costs exceed the then-current year's threshold must be compensated by Hoechst. No payments have yet become due under this rule.

Hoechst must indemnify Clariant indefinitely (i) with respect to sites taken over by Clariant, for costs which relate to environmental pollutions attributable to certain activities of Hoechst or of third parties, (ii) for costs attributable to four defined waste deposit sites in Germany which are located outside the sites taken over by Clariant (to the extent exceeding an indexed amount of approximately 20.5 million), (iii) for costs from certain locally concentrated pollutions in the sites taken over by Clariant but not caused by specialty chemicals activities in the past, and (iv) for 75% of the costs relating to a specific waste deposit site in Frankfurt, Germany.

*InfraServ Höchst Retained Liabilities*

By the Asset Contribution Agreement dated December 19/20, 1996, as amended in 1997, Hoechst contributed all lands, buildings, and related assets of the Hoechst site at Frankfurt-Höchst to InfraServ Höchst GmbH & Co. KG. InfraServ Höchst undertook to indemnify Hoechst against environmental liabilities at the Höchst site and with respect to certain landfills. As consideration for the indemnification undertaking, Hoechst transferred to InfraServ approximately 57 million to fund reserves. In 1997, Hoechst also agreed it would reimburse current and future InfraServ Höchst environmental expenses up to 143 million. As a former owner of the land and as a former user of the landfills, Hoechst may ultimately be liable for costs of remedial action in excess of this amount.

**D.23. Provisions for discounts, rebates and sales returns**

Adjustments between gross sales and net sales, as described in Note B.14., are recognized either as provisions or as reductions in accounts receivable, depending on their nature.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows movements in these items:

( million)	Government and State programs (2)	Managed Care and GPO programs (3)	Charge- back incentives	Rebates and discounts	Sales returns	Other deductions	Total
<b>January 1, 2009</b>	<b>286</b>	<b>185</b>	<b>82</b>	<b>261</b>	<b>183</b>	<b>52</b>	<b>1,049</b>
Current provision related to current period sales	566	433	904	2,036	204	128	4,271
Net change in provision related to prior period sales	19	7		12	(7)		31
Payments made	(477)	(431)	(903)	(1,893)	(175)	(136)	(4,015)
Currency Translation differences	(8)	(7)	(3)	9	(3)	2	(10)
<b>December 31, 2009</b>	<b>386</b>	<b>187</b>	<b>80</b>	<b>425</b>	<b>202</b>	<b>46</b>	<b>1,326</b>
Current provision related to current period sales	937	410	1,246	3,058	357	127	6,135
Net change in provision related to prior period sales	(4)	(11)	8	14	12	(4)	15
Payments made	(663)	(400)	(1,225)	(2,719)	(255)	(126)	(5,388)
Currency Translation differences	16	15	6	35	17	5	94
<b>December 31, 2010</b>	<b>672</b>	<b>201</b>	<b>115</b>	<b>813</b>	<b>333</b>	<b>48</b>	<b>2,182</b>
Merial <sup>(1)</sup>			1	69	1	8	79
Genzyme	7		4	132	39	12	194
Current provision related to current period sales	1,224	496	1,569	4,075	348	152	7,864
Net change in provisions related to prior period sales	(5)	(35)	13	22	(4)	(2)	(11)
Payments made	(1,125)	(466)	(1,548)	(3,897)	(311)	(125)	(7,472)
Currency Translation differences	18	7	6	(9)	9	3	34
<b>Balance at December 31, 2011</b>	<b>791</b>	<b>203</b>	<b>160</b>	<b>1,205</b>	<b>415</b>	<b>96</b>	<b>2,870</b>

(1) This line includes the provisions for Merial customer rebated and returns, previously registered as Liabilities on assets held for sale or exchange, which were reclassified following the announcement that to maintain two separate entities (Merial and Intervet/Schering-Plough) operating independently (see notes D.2. et D.8.1.).

(2) Primarily the U.S. government's Medicare and Medicaid programs.

(3) Rebates and other price reductions, primarily granted to healthcare authorities in the United States.

**D.24. Personnel costs**

Total personnel costs break down as follows:

( million)	Year ended December 31, 2011	Year ended December 31, 2010 <sup>(1)</sup>	Year ended December 31, 2009 <sup>(1)</sup>
Salaries	5,940	5,121	5,019

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Social security charges (including defined-contribution pension plans)	1,716	1,555	1,510
Stock options and other share-based payment expense	143	133	114
Defined-benefit pension plans	358	340	404
Other employee benefits	262	238	233
<b>Total</b>	<b>8,419</b>	<b>7,387</b>	<b>7,280</b>

(1) Excluding Meril.

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The total number of employees at December 31, 2011 was 113,719, compared with 101,575 at December 31, 2010 and 104,867 at December 31, 2009 (these employee numbers are unaudited).

Employee numbers by function as of December 31 are shown below (unaudited):

	<b>December 31, 2011</b>	<b>December 31, 2010 <sup>(1)</sup></b>	<b>December 31, 2009 <sup>(1)</sup></b>
Production	44,415	37,504	36,849
Research and development	18,823	16,983	19,132
Sales force	32,874	32,686	34,292
Marketing and support functions	17,607	14,402	14,594
<b>Total</b>	<b>113,719</b>	<b>101,575</b>	<b>104,867</b>

<sup>(1)</sup> Excluding Meril.

**D.25. Other operating income**

Other operating income amounted to 319 million in 2011, compared with 369 million in 2010 and 861 million in 2009.

This line includes income arising under alliance agreements in the Pharmaceuticals segment ( 202 million in 2011 versus 315 million in 2010 and 646 million in 2009), in particular the agreement on the worldwide development and marketing of Actonel<sup>®</sup> (see Note C.2.) and the Group's share of profits on Copaxone<sup>®</sup> in 2010 and 2009.

It also includes operating foreign exchange gains and losses, representing a net loss of (5) million in 2011, compared with a net loss of (141) million in 2010 and a net gain of 40 million in 2009 and proceeds from disposals related to ongoing operations, which amounted to 56 million in 2011, 54 million in 2010, and 56 million in 2009.

**D.26. Other operating expenses**

Other operating expenses amounted to 315 million in 2011, versus 292 million in 2010 and 481 million in 2009. This item includes shares of profits due to alliance partners (other than BMS and the Alliance Partner under the Actonel<sup>®</sup> agreement) under product marketing agreements, primarily in Europe, Japan, the United States and Canada ( 121 million in 2011, 169 million in 2010, and 186 million in 2009).

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The costs for the Genzyme acquisition recognized in 2011 as other operating expenses amounted 65 million (see Note D.1.1.).

This item also includes, for 2011, an expense of 43 million ( 51 million in 2010) relating to pensions and other benefits for Group retirees.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.27. Restructuring costs**

Restructuring costs recognized in 2011 amounted to 1,314 million, ( 1,384 million in 2010 and 1,080 million in 2009) and break down as follows:

( million)	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31, 2009
Employee-related expenses	840	817	869
Expenses related to property, plant and equipment	422	184	146
Compensation for early termination of contracts (other than contracts of employment)	27	35	19
Decontamination costs	22	105	30
Other restructuring costs	3	243	16
<b>Total</b>	<b>1,314</b>	<b>1,384</b>	<b>1,080</b>

The restructuring costs reflect measures announced by the Group to implement a major transformation project initiated in 2009 to adapt the group's entities to future challenges.

The restructuring costs recognized in 2011 primarily reflect:

the geographic transformation and reorganization of Research and Development operations as part of a global project that affects the United States, Japan, Germany, Italy, the United Kingdom and Hungary;

the measures announced by Sanofi in 2011 to adapt its industrial facilities in Europe, particularly production and distribution sites in order to optimize the management of flows in the pharmaceutical business;

the continuation of the measures taken by the Group to adjust its sales force in the United States and a number of European countries;

the implementation of shared services and MCO (Multi-Country Organisations) in Europe;

integration of the Genzyme teams around the world.

In 2010, restructuring costs related primarily to measures announced by the Group aimed at transforming the Research and Development operations to upgrade its chemical manufacturing sites to biotech and vaccine production, and to reorganize its sales form in the United States and Europe. These costs also include the impact of retirement reform on the CAA plans already existing in France.

In 2009, restructuring costs related primarily to measures announced in June 2009 by the Group to transform the Research and Development operations in France in order to promote innovation and adapt central support functions to streamline the organization. These costs essentially represent personnel expenses for early retirement benefits and early termination indemnities under voluntary departure plans. In France, approximately 1,000 jobs in Research and Development and 450 jobs in support functions are affected.

**D.28. Other gains and losses, and litigation**

Other gains and losses at December 31, 2011 include:

the expense resulting primarily from the backlog of depreciation and amortization charged against the Merial property, plant and equipment and other intangible assets for the period from September 18, 2009 to December 31, 2010, which amounted to 519 million (see Note D.2.).

the impact of the sale of the Dermik dermatology business in the amount of (18) million before tax.

In 2011, this line item also includes a 210 million income for the indemnification of a loss caused by the marketing of a counterfeit generic version of Plavix® in the United States in 2006.

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In 2010, this line item reported an expense of 138 million, relating to an adjustment to vendor's guarantee provisions in connection with past divestments.

The Group made no major divestments in 2010 or 2009.

**D.29. Financial income and expenses**

Financial income and expenses break down as follows:

<i>( million)</i>	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31, 2009
Cost of debt <sup>(1)</sup>	(425)	(385)	(310)
Interest income	100	61	88
<b>Cost of debt, net of cash and cash equivalents</b>	<b>(325)</b>	<b>(324)</b>	<b>(222)</b>
Non-operating foreign exchange gains/(losses)	10	(20)	(67)
Unwinding of discount on provisions <sup>(2)</sup>	(83)	(68)	(42)
Gains/(losses) on disposals of financial assets	25	61	3
Impairment losses on financial assets, net of reversals <sup>(3)</sup>	(58)	(6)	(2)
Other items	19	(5)	32
<b>Net financial income/(expenses)</b>	<b>(412)</b>	<b>(362)</b>	<b>(298)</b>
<i>comprising: Financial expenses</i>	<i>(552)</i>	<i>(468)</i>	<i>(325)</i>
<i>Financial income</i>	<i>140</i>	<i>106</i>	<i>27</i>

<sup>(1)</sup> Includes gains/losses on interest rate derivatives used to hedge debt: 47 million gain in 2011, 7 million gain in 2010, 25 million gain in 2009.

<sup>(2)</sup> Primarily provisions for environmental risks.

<sup>(3)</sup> Primarily available-for-sale financial asset, including 49 million related to Greek sovereign bonds in 2011.

In 2011, 2010 and 2009, the impact of the ineffective portion of hedging relationships was not material.

**D.30. Income tax expense**

The Group has opted for tax consolidations in a number of countries, principally France, Germany, the United Kingdom and the United States.

The table below shows the split of income tax expense between current and deferred taxes:

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<i>( million)</i>	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31, 2009
Current taxes	(2,359)	(2,929)	(2,551)
Deferred taxes	1,904	1,499	1,152
<b>Total</b>	<b>(455)</b>	<b>(1,430)</b>	<b>(1,399)</b>

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The difference between the effective tax rate and the standard corporate income tax rate applicable in France is explained as follows:

<i>(as a percentage)</i>	<b>Year ended December 31, 2011</b>	<b>Year ended December 31, 2010</b>	<b>Year ended December 31, 2009</b>
Standard tax rate applicable in France	34	34	34
Impact of reduced-rate income tax on royalties in France	(11)	(10)	(8)
Impact of change in net deferred tax liabilities as a result of changes in tax laws and rates <sup>(1)</sup>	(4)		1
Impact of the French-American Advance Pricing Agreement (APA) 2006-2010	(7)		
Impact of the ratification of the Franco-American treaty on deferred tax liabilities relating to tax cost of distributions made from reserves			(2)
Impact of tax borne by BMS for the territory managed by Sanofi (see Note D.32.)	(1)	(2)	(3)
Other items	(2)	1	1
<b>Effective tax rate</b>	<b>9</b>	<b>23</b>	<b>23</b>

<sup>(1)</sup> In 2011, primarily the change in UK laws and, in 2009, the reform of local business taxes in France.

The Other items line includes (i) the effect of differences between tax rates applicable in France and those applicable in other jurisdictions; (ii) the impact of the new CVAE valued added business tax in France from January 1, 2010 and the impact of the reassessment of some of the Group's tax risks. In 2011, this line item also included a 48 million impact related to the recognition of deferred tax assets not booked initially at the time of business combinations (compared with 3 million in 2010).

In December 2011, the French and American governments entered into an Advance Pricing Agreement (APA) for fiscal years 2006 to 2011. The APA procedure is one in which tax authorities from several countries negotiate and conclude an agreement for a prospective period to determine transfer pricing methods applicable to transactions between subsidiaries of the same parent company.

**D.31. Share of profit/loss of associates and joint ventures**

This item mainly comprises the share of co-promotion profits attributable to Sanofi for territories covered by entities majority-owned by BMS (see Note C.1.). The impact of the BMS alliance in 2011 was 1,671 million, before deducting the tax effect of 601 million (versus 1,551 million in 2010 with a tax effect of 571 million and 1,229 million, tax effect of 444 million in 2009).

It also includes the share of profits or losses from other associates and joint ventures for non-significant amounts in 2011 and 2010 and for 168 million in 2009, an amount that includes the effects of the Aventis acquisition (amortization and impairment other intangible assets).

**D.32. Net income attributable to non-controlling interests**

This line includes the share of co-promotion profits attributable to BMS for territories covered by entities majority-owned by the Group (see Note C.1.). The amount was 226 million in 2011, 237 million in 2010, and 405 million in 2009.

There is no tax effect, because BMS receives its share before tax.

It also includes the share of net income attributable to other non-controlling interests for 15 million in 2011, 17 million in 2010, and 21 million in 2009.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.33. Related party transactions**

The principal related parties of Sanofi are companies over which the Group has control or significant influence, joint ventures, key management personnel, and principal shareholders.

The Group has not entered into any transactions with any key management personnel. Financial relations with the Group's principal shareholders, in particular the Total group, fall within the ordinary course of business and were immaterial in the years ended December 31, 2011, December 31, 2010 and December 31, 2009.

The list of companies the Group controls is presented in Note F.1. These companies are fully consolidated as described in Note B.1., and the transactions between these companies, and between the parent company and its subsidiaries, are eliminated when preparing the consolidated financial statements.

Transactions concluded with companies over which the Group has significant influence and with joint ventures are presented in Note D.6.

Key management personnel include corporate officers (including two directors during 2011, three directors in 2010 and 2009, covered by supplementary pension plans: see Item 6.B.) and the members of the Executive Committee (9 members during 2011, 2010 and 2009.)

The table below shows, by type, the compensation paid to key management personnel:

<i>( million)</i>	<b>Year ended December 31, 2011</b>	<b>Year ended December 31, 2010</b>	<b>Year ended December 31, 2009</b>
Short-term benefits <sup>(1)</sup>	21	23	22
Post-employment benefits	10	12	11
Share-based payment <sup>(2)</sup>	5	6	5
<b>Total recognized in the income statement</b>	<b>36</b>	<b>41</b>	<b>38</b>

<sup>(1)</sup> Compensation, employer's social security contributions, directors' attendance fees, and any termination benefits.

<sup>(2)</sup> Stock option expense computed using the Black-Scholes model.

The aggregate amount of supplementary pension obligations to corporate officers and key management personnel was 121 million at December 31, 2011 compared with 130 million at December 31, 2010 and 149 million at December 31, 2009. The aggregate amount of retirement benefits payable to corporate officers and key management personnel was 5 million at December 31, 2011 and 2010 and 10 million at

December 31, 2009.

**D.34. Split of net sales**

Credit risk is the risk that customers (wholesalers, distributors, pharmacies, hospitals, clinics or government agencies) may fail to pay their debts. The Group manages credit risk by pre-vetting customers in order to set credit limits and risk levels and asking for guarantees or insurance where necessary, performing controls, and monitoring qualitative and quantitative indicators of accounts receivable balances such as the period of credit taken and overdue payments.

Customer credit risk also arises as a result of the concentration of the Group's sales with its largest customers, in particular certain wholesalers in the United States. The Group's three largest customers respectively accounted for approximately 6.8%, 5.5% and 5.1% of gross revenues in 2011.

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**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Net sales*

Net sales of Sanofi comprise net sales generated by the Pharmaceuticals segment, the Vaccines segment and the Animal Health segment. The table below shows sales of flagship products and other major pharmaceuticals products:

<i>( million)</i>	Year ended December 31,		
	2011	2010	2009
Lantus®	3,916	3,510	3,080
Apidra®	190	177	137
Insuman®	132	133	131
Amaryl®	436	478	416
Other diabetes products	10		
<b>Sub-total: Diabetes</b>	<b>4,684</b>	<b>4,298</b>	<b>3,764</b>
Lovenox®	2,111	2,806	3,043
Plavix®	2,040	2,083	2,623
Taxotere®	922	2,122	2,177
Aprovel®	1,291	1,327	1,236
Eloxatine®	1,071	427	957
Multaq®	261	172	25
Jevtana®	188	82	
Stilnox®/ Ambien®/ Ambien® CR/ Myslee®	490	819	873
Allegra®	580	607	731
Copaxone®	436	513	467
Tritace®	375	410	429
Depakine®	388	372	329
Xatral®	200	296	296
Actonel®	167	238	264
Nasacort®	106	189	220
<b>Other Products</b>	<b>5,773</b>	<b>6,064</b>	<b>5,947</b>
<b>Consumer Health Care</b>	<b>2,666</b>	<b>2,217</b>	<b>1,430</b>
<b>Generics</b>	<b>1,746</b>	<b>1,534</b>	<b>1,012</b>
Cerezyme®	441		
Myozyme® / Lumizyme®	308		
Fabrazyme®	109		
Renagel® / Renvela®	415		
SynVisc®	256		
Other Genzyme products	866		
<b>Genzyme sub-total <sup>(1)</sup></b>	<b>2,395</b>		
<b>Total Pharmaceuticals</b>	<b>27,890</b>	<b>26,576</b>	<b>25,823</b>

(1) Since the acquisition date (as of April 2011).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Net sales of the principal product ranges of the Vaccines segment are shown below:

( million)	Year ended December 31,		
	2011	2010	2009
Influenza Vaccines	826	1,297	1,062
of which seasonal vaccines	826	845	597
of which pandemic vaccines		452	465
Pediatric Combination and Poliomyelitis Vaccines	1,075	984	968
Meningitis/Pneumonia Vaccines	510	527	538
Adult Booster Vaccines	465	449	406
Travel and Endemics Vaccines	370	382	313
Other Vaccines	223	169	196
<b>Total Vaccines</b>	<b>3,469</b>	<b>3,808</b>	<b>3,483</b>

For the Animal Health segment, net sales of the primary products are shown below:

( million)	2011	2010	2009 <sup>(1)</sup>
Frontline® and other fipronil-based products	764	774	195
Vaccines	662	627	131
Avermectine	372	355	90
Other Animal Health products	232	227	63
<b>Total Animal Health</b>	<b>2,030</b>	<b>1,983</b>	<b>479</b>

<sup>(1)</sup> Since September 18, 2009.

**D.35. Segment information**

As indicated in Note B.26., Sanofi has the following operating segments: Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health. All other activities are combined in a separate segment, Other.

In March 2011, Sanofi and Merck announced the mutual termination of their agreement to create a new Animal Health joint venture. Following this announcement, the Animal Health business has been identified as an operating segment on the basis of information now used internally by Management to measure operational performance and to allocate resources.

The Pharmaceuticals segment covers research, development, production and marketing of medicines, including those coming from Genzyme (see D.1.1.). The Sanofi pharmaceuticals portfolio consists of flagship products, plus a broad range of prescription medicines, generic medicines, and consumer health products. This segment also includes all associates whose activities are related to pharmaceuticals, in particular the entities

majority owned by BMS.

The Vaccines segment is wholly dedicated to vaccines, including research, development, production and marketing. This segment includes the Sanofi Pasteur MSD joint venture.

The Animal Health segment comprises the research, development, production and marketing activities of Merial, which offers a complete range of medicines and vaccines for a wide variety of animal species.

The Other segment includes all activities that do not qualify as reportable segments under IFRS 8. This segment includes the Group's interest in the Yves Rocher group, until the date of significant influence loss (see D.6.) and effects of retained commitments in respect of divested activities.

Inter-segment transactions are not material.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.35.1. Segment results**

Sanofi reports segment results on the basis of Business operating income. This indicator, (compliant with IFRS 8) is used internally to measure operational performance and allocate resources.

Business operating income is derived from *Operating income*, adjusted as follows:

the amounts reported in the line items *Restructuring costs, Fair value remeasurement of contingent consideration liabilities* and *Other gains and losses, and litigation* are eliminated;

amortization and impairment losses charged against intangible assets (other than software) are eliminated;

the share of profits/losses of associates and joint ventures is added;

the share attributable to non-controlling interests is deducted;

other acquisition-related effects (primarily the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated;

restructuring costs relating to associates and joint ventures are eliminated.

Segment results are shown in the tables below:

( million)	Year ended December 31, 2011				Total
	Pharmaceuticals	Vaccines	Animal Health	Other	
<b>Net sales</b>	<b>27,890</b>	<b>3,469</b>	<b>2,030</b>		<b>33,389</b>
Other revenues	1,622	25	22		1,669
Cost of sales	(8,368)	(1,404)	(654)		(10,426)
Research and development expenses	(4,101)	(564)	(146)		(4,811)
Selling and general expenses	(7,376)	(542)	(617)	(1)	(8,536)
Other operating income and expenses	(13)		(7)	24	4
Share of profit/(loss) of associates and joint ventures	1,088	1		13	1,102
Attributable to non-controlling interests	(246)		(1)		(247)
<b>Business operating income</b>	<b>10,496</b>	<b>985</b>	<b>627</b>	<b>36</b>	<b>12,144</b>
Financial income and expenses					(412)
Income tax expense					(2,937)
<b>Business net income</b>					<b>8,795</b>



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

( million)	Year ended December 31, 2010 <sup>(1)</sup>				Total
	Pharmaceuticals	Vaccines	Animal Health	Other	
<b>Net sales</b>	<b>26,576</b>	<b>3,808</b>	<b>1,983</b>		<b>32,367</b>
Other revenues	1,623	28	18		1,669
Cost of sales	(7,316)	(1,371)	(615)		(9,302)
Research and development expenses	(3,884)	(517)	(155)		(4,556)
Selling and general expenses	(6,962)	(603)	(604)	(2)	(8,171)
Other operating income and expenses	177	14	(6)	(108)	77
Share of profit/(loss) of associates and joint ventures	1,009	19		8	1,036
Attributable to non-controlling interests	(258)	1			(257)
<b>Business operating income</b>	<b>10,965</b>	<b>1,379</b>	<b>621</b>	<b>(102)</b>	<b>12,863</b>
Financial income and expenses					(362)
Income tax expense					(3,286)
<b>Business net income</b>					<b>9,215</b>

<sup>(1)</sup> The results of Merial operations, previously reported as held-for-exchange, have been reclassified and included in net income of continuing operations in accordance with IFRS 5.36., following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separate businesses operating independently (see Notes D.2. and D.8.1.).

( million)	Year ended December 31, 2009 <sup>(1)</sup>				Total
	Pharmaceuticals	Vaccines	Animal Health	Other	
<b>Net sales</b>	<b>25,823</b>	<b>3,483</b>	<b>479</b>		<b>29,785</b>
Other revenues	1,412	31	4		1,447
Cost of sales	(6,527)	(1,326)	(176)		(8,029)
Research and development expenses	(4,091)	(491)	(46)		(4,628)
Selling and general expenses	(6,762)	(561)	(146)	(2)	(7,471)
Other operating income and expenses	387	(3)	(5)	1	380
Share of profit/(loss) of associates and joint ventures	792	41	178 <sup>(2)</sup>	8	1,019
Attributable to non-controlling interests	(426)	(1)			(427)
<b>Business operating income</b>	<b>10,608</b>	<b>1,173</b>	<b>288</b>	<b>7</b>	<b>12,076</b>
Financial income and expenses					(298)
Income tax expense					(3,149)
<b>Business net income</b>					<b>8,629</b>

<sup>(1)</sup> The results of Merial operations, previously reported as held-for-exchange, have been reclassified and included in net income of continuing operations in accordance with IFRS 5.36., following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separate businesses operating independently (see Notes D.2. and D.8.1.).

<sup>(2)</sup> Including Merial until September 17, 2009

Business net income is determined by taking Business operating income and adding financial income and deducting financial expenses, including the related income tax effects.

Business net income is defined as *Net income attributable to equity holders of Sanofi* excluding (i) amortization of intangible assets; (ii) impairment of intangible assets; (iii) Fair value remeasurement of contingent consideration liabilities, (iv) other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures); (v) restructuring costs (including restructuring costs relating to associates and joint ventures), (vi) other gains and losses, and litigation; (vii) the impact resulting from the absence of amortization of the Merial tangible assets in 2010 and starting September 18, 2009 (in accordance





**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

with IFRS 5), (viii) the tax effect related to the items listed above and (ix) effects of major tax disputes and, as an exception for 2011, the retroactive effect (2006-2010) on the tax liability resulting from the agreement signed on December 22, 2011 by France and the United States on transfer prices (APA-Advance Pricing Agreement), for which the amount is deemed to be significant, and (x) the share of non-controlling interests in items (i) through (ix). The items listed in (iii), (v) and (vi) correspond to those reported in the income statement line items *Fair value remeasurement of contingent consideration liabilities, Restructuring costs, and Other gains and losses, and litigation*.

The table below shows the reconciliation between Business net income and *Net income attributed to equity holders of Sanofi*:

( million)	Year ended December 31, 2011	Year ended December 31, 2010 <sup>(1)</sup>	Year ended December 31, 2009 <sup>(1)</sup>
<b>Business net income</b>	<b>8,795</b>	<b>9,215</b>	<b>8,629</b>
(i) Amortization of intangible assets	(3,314)	(3,529)	(3,528)
(ii) Impairment of intangible assets	(142)	(433)	(372)
(iii) Fair value remeasurement of contingent consideration liabilities	15		
(iv) Expenses arising from the impact of acquisitions on inventories <sup>(2)</sup>	(476)	(142)	(90)
(v) Restructuring costs	(1,314)	(1,384)	(1,080)
(vi) Other gains and losses, and litigation <sup>(3)</sup>	(327)	(138)	
(vii) Impact of the non depreciation of property, plant and equipment of Merial (in accordance with IFRS 5)		77	21
(viii) Tax effects of:	1,905	1,856	1,644
<i>amortization of intangible assets</i>	<i>1,178</i>	<i>1,183</i>	<i>1,130</i>
<i>impairment of intangible assets</i>	<i>37</i>	<i>143</i>	<i>136</i>
<i>Fair value remeasurement of contingent consideration liabilities</i>	<i>34</i>		
<i>expenses arising from the impact of acquisitions on inventories</i>	<i>143</i>	<i>44</i>	<i>24</i>
<i>restructuring costs</i>	<i>399</i>	<i>466</i>	<i>360</i>
<i>other gains and losses, and litigation</i>	<i>114</i>	<i>46</i>	
<i>non depreciation of property, plant and equipment of Merial (IFRS 5)</i>		<i>(26)</i>	<i>(6)</i>
(iv)/(ix) Other tax items	577 <sup>(4)</sup>		106
(x) Share of items listed above attributable to non-controlling interests	6	3	1
(iv)/(v) Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures <sup>(5)</sup>	(32)	(58)	(66)
<b>Net income attributable to equity holders of Sanofi</b>	<b>5,693</b>	<b>5,467</b>	<b>5,265</b>

<sup>(1)</sup> The results of the Merial operations previously presented as asset held for exchange were reclassified and included in the net income from continuing operations, in accordance with IFRS 5.36., following the announcement to maintain two separate (Merial and Intervet/Schering-Plough) operating independently (see Notes D.2. and D.8.1.).

<sup>(2)</sup> This line item corresponds to the impact of workdown of inventories remeasured at fair value at the acquisition date.

<sup>(3)</sup> See Note D.28.

<sup>(4)</sup> In 2011, related to Advance Pricing Agreement impact for 349 million and 228 million reflecting a decrease in deferred tax liabilities linked to revaluation of intangible assets following changes in tax laws.

<sup>(5)</sup> This line item represents the share of major restructuring costs recognized by associates and joint ventures and expenses resulting from the impact of acquisitions on associates and joint ventures (workdown of inventories acquired, amortization and impairment of intangible assets, and impairment of goodwill).



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.35.2. Other segment information**

The tables below show the split by operating segment of (i) the carrying amount of investments in associates and joint ventures, (ii) acquisitions of property, plant and equipment, and (iii) acquisitions of intangible assets.

The principal associates and joint ventures are: for the Pharmaceuticals segment, the entities majority owned by BMS (see Note C.1.), Handok, InfraServ Höchst, for the Vaccines segment, Sanofi Pasteur MSD. The Other segment includes the equity associate Yves Rocher, which is no longer recognized using the equity method as of November 2011 (see note D.6.).

Acquisitions of intangible assets and property, plant and equipment correspond to acquisitions made during the period.

<i>( million)</i>	<b>Pharmaceuticals</b>	<b>Vaccines</b>	<b>2011 Animal Health</b>	<b>Other</b>	<b>Total</b>
Investments in associates and joint ventures	488	319			807
Acquisitions of property, plant and equipment	1,136	323	77		1,536
Acquisitions of intangible assets	223	8	15		246

<i>( million)</i>	<b>Pharmaceuticals</b>	<b>Vaccines</b>	<b>2010 Animal Health</b>	<b>Other</b>	<b>Total</b>
Investments in associates and joint ventures	446	350		128	924
Acquisitions of property, plant and equipment	779	416	88		1,283
Acquisitions of intangible assets	335	43	1		379

<i>( million)</i>	<b>Pharmaceuticals</b>	<b>Vaccines</b>	<b>2009 Animal Health</b>	<b>Other</b>	<b>Total</b>
Investments in associates and joint ventures	420	412	5	123	960
Acquisitions of property, plant and equipment	940	465	33		1,438
Acquisitions of intangible assets	364	16	8		388

**D.35.3. Information by geographical region**

The geographical information on net sales provided below is based on the geographical location of the customer.

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In accordance with IFRS 8, the non-current assets reported below exclude financial instruments, deferred tax assets, and pre-funded pension obligations.

<i>( million)</i>	<b>2011</b>					
	<b>Total</b>	<b>Europe</b>	<i>of which France</i>	<b>North America</b>	<i>of which United States</i>	<b>Other countries</b>
Net sales	33,389	11,796	3,106	10,511	9,957	11,082
Non-current assets:						
property, plant and equipment	10,750	6,857	4,128	2,768	2,374	1,125
intangible assets	23,639	5,537		15,422		2,680
goodwill	38,079	15,072		16,209		6,798

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( million)	2010					
	Total	Europe	of which France	North America	of which United States	Other countries
Net sales <sup>(1)</sup>	32,367	12,198	3,092	10,333	9,790	9,836
Non-current assets:						
property, plant and equipment	8,155	5,764	3,603	1,510	1,091	881
intangible assets	12,479	3,773		5,835		2,871
goodwill	31,932	13,718		13,264		4,950

<sup>(1)</sup> The Merial results previously presented as asset held for exchange were reclassified and included in the net income from continuing operations, in accordance with IFRS 5.36., following the announcement that two separate entities (Merial and Intervet/Schering-Plough) operating independently would be maintained (see notes D.2. and D.8.1.).

( million)	2009					
	Total	Europe	of which France	North America	of which United States	Other countries
Net sales <sup>(1)</sup>	29,785	12,237	3,261	10,021	9,573	7,527
Non-current assets:						
property, plant and equipment	7,830	5,734	3,436	1,375	1,018	721
intangible assets	13,747	4,636		5,930		3,181
goodwill	29,733	13,528		11,419		4,786

<sup>(1)</sup> The Merial results previously presented as asset held for exchange were reclassified and included in the net income from continuing operations, in accordance with IFRS 5.36., following the announcement that two separate entities (Merial and Intervet/Schering-Plough) operating independently would be maintained (see notes D.2. and D.8.1.).

As described in Note D.5. to the consolidated financial statements, France is not a cash-generating unit. Consequently, information about goodwill is provided for Europe.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****E. PRINCIPAL ACCOUNTANTS FEES AND SERVICES***

PricewaterhouseCoopers Audit and Ernst & Young Audit served as independent auditors of Sanofi for the year ended December 31, 2011 and for all other reporting periods covered by this annual report on Form 20-F. The table below shows fees charged by these firms and member firms of their networks to Sanofi and other consolidated companies in the years ended December 31, 2011 and 2010.

( million)	Ernst & Young				PricewaterhouseCoopers			
	2011 Amount	%	2010 Amount	%	2011 Amount	%	2010 Amount	%
<b>Audit</b>								
<b>Audit opinion, review of statutory and consolidated financial statements</b> <sup>(1)</sup>	<b>13.6</b>	<b>92%</b>	<b>12.8</b>	<b>92%</b>	<b>17.9</b>	<b>91%</b>	<b>13.5</b>	<b>93%</b>
<i>Sanofi S.A.</i>	3.5		3.7		4.1		3.7	
<i>fully consolidated subsidiaries</i>	10.1		9.1		13.8		9.8	
<b>Other audit-related services</b> <sup>(2)</sup>	<b>1.0</b>	<b>7%</b>	<b>1.0</b>	<b>7%</b>	<b>1.3</b>	<b>7%</b>	<b>0.7</b>	<b>5%</b>
<i>Sanofi S.A.</i>	0.3				0.9			
<i>fully consolidated subsidiaries</i>	0.7		1.0		0.4		0.7	
<b>Sub-total</b>	<b>14.6</b>	<b>99%</b>	<b>13.8</b>	<b>99%</b>	<b>19.2</b>	<b>98%</b>	<b>14.2</b>	<b>98%</b>
<b>Non-audit services</b>								
Tax	0.1		0.1		0.4		0.3	
Other								
<b>Sub-total</b>	<b>0.1</b>	<b>1%</b>	<b>0.1</b>	<b>1%</b>	<b>0.4</b>	<b>2%</b>	<b>0.3</b>	<b>2%</b>
<b>TOTAL</b>	<b>14.7</b>	<b>100%</b>	<b>13.9</b>	<b>100%</b>	<b>19.6</b>	<b>100%</b>	<b>14.5</b>	<b>100%</b>

<sup>(1)</sup> Professional services rendered for the audit and review of the consolidated financial statements of Sanofi, statutory audits of the financial statements for the years ended December 31, 2011 and 2010 of Sanofi and its subsidiaries, compliance with local regulations, and review of documents filed with the AMF and the SEC (including services normally provided by independent experts of the audit firms in connection with the audit).

<sup>(2)</sup> Services that are normally performed by the independent accountants, ancillary to audit services.

**Audit Committee Pre-approval and Procedures**

The Group Audit Committee has adopted a policy and established certain procedures for the pre-approval of audit and other permitted audit-related services, and for the pre-approval of permitted non-audit services to be provided by the independent auditors. In 2011, the Audit Committee established a budget breaking down permitted audit-related services and non-audit services, and the related fees to be paid.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****F. LIST OF PRINCIPAL COMPANIES INCLUDED IN THE CONSOLIDATION FOR THE YEAR ENDED DECEMBER 31, 2011****F.1. Principal fully consolidated companies**

The principal companies in the Group's areas of operations and business segments are:

		<b>Financial interest</b>
		<b>%</b>
<i>Europe</i>		
Aventis Beteiligungsverwaltung GmbH	Germany	100
Sanofi-Aventis Deutschland GmbH	Germany	100
Hoechst GmbH	Germany	100
Winthrop Arzneimittel GmbH	Germany	100
Zentiva Inhalationsprodukte GmbH	Germany	100
Merial GmbH	Germany	100
Sanofi-Aventis GmbH / Bristol-Myers Squibb GesmbH OHG <sup>(1)</sup>	Austria	50.1
Sanofi-Aventis GmbH	Austria	100
Sanofi-Aventis Belgium S.A.N.V.	Belgium	100
Merial Norden A/S	Denmark	100
Sanofi-Aventis Denmark A/S	Denmark	100
Sanofi Winthrop BMS partnership (JV DK) <sup>(1)</sup>	Denmark	50.1
Merial Laboratorios S.A.	Spain	100
Sanofi-Aventis SA	Spain	100
Sanofi Winthrop BMS OY <sup>(1)</sup>	Finland	50.1
Sanofi-Aventis OY	Finland	100
Sanofi-Aventis Europe S.A.S.	France	100
Sanofi-Aventis Participations S.A.S.	France	100
Sanofi Pasteur Participations S.A.	France	100
Sanofi-Aventis Amérique du Nord S.A.S.	France	100
Sanofi Pasteur Holding S.A.S.	France	100
Aventis Pharma S.A.	France	100
Sanofi Pasteur S.A.	France	100
Aventis Agriculture S.A.	France	100
Fovea Pharmaceuticals S.A.	France	100
Francopia S.A.R.L.	France	100
Winthrop Médicaments S.A.	France	100
Sanofi Chimie S.A.	France	100
Sanofi Participations S.A.S.	France	100
Sanofi Pharma Bristol-Myers Squibb S.N.C. <sup>(1)</sup>	France	50.1
Sanofi	France	100
Sanofi-Aventis France S.A.	France	100
Sanofi-Aventis Groupe S.A.	France	100
Sanofi-Aventis Recherche et Développement S.A.	France	100
Sanofi Winthrop Industrie S.A.	France	100
Laboratoire Oenobiol S.A.S.	France	100
Merial S.A.S.	France	100
Chattem Greece S.A.	Greece	100



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Sanofi-Aventis A.E.B.E.	Greece	100
Chinoin Private Co. Ltd	Hungary	99.6
Sanofi-Aventis Private Co. Ltd	Hungary	99.6
Chattem Global Consumer Products Limited	Ireland	100
Carraig Insurance Ltd	Ireland	100
Sanofi-Aventis Ireland Ltd	Ireland	100
Merial Italia S.p.A.	Italy	100
Sanofi-Aventis SpA	Italy	100
Sanofi-Aventis Norge AS	Norway	100
Sanofi Winthrop BMS partnership ANS <sup>(1)</sup>	Norway	50.1
Sanofi-Aventis Netherlands B.V.	Netherlands	100
Sanofi Winthrop BMS VOF <sup>(1)</sup>	Netherlands	50.1
Sanofi-Aventis Sp z.o.o.	Poland	100

<sup>(1)</sup> Partnership with Bristol-Myers Squibb (see Note C.1.).

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		<b>Financial interest</b>
		<b>%</b>
<i>Europe</i>		
Nepentes S.A.	Poland	100
Winthrop Farmaceutica Portugal LDA	Portugal	100
Sanofi-Aventis Produtos Farmaceuticos LDA	Portugal	100
Sanofi Winthrop Bristol Myers Squibb AEIE <sup>(1)</sup>	Portugal	50.1
Sanofi-Aventis s.r.o.	Czech Republic	100
Zentiva Group a.s.	Czech Republic	100
Sanofi-Aventis Romania SRL	Romania	100
Aventis Pharma Ltd	United Kingdom	100
Chattem (U.K.) Limited	United Kingdom	100
Sanofi Aventis UK Holdings Limited	United Kingdom	100
Sanofi Pasteur Holding Ltd	United Kingdom	100
Sanofi-Synthélabo Ltd	United Kingdom	100
Sanofi-Synthélabo UK Ltd	United Kingdom	100
Winthrop Pharmaceuticals UK Ltd	United Kingdom	100
Fisons Limited	United Kingdom	100
May and Baker Limited	United Kingdom	100
Merial Limited	United Kingdom	100
Merial Animal Health Limited	United Kingdom	100
ZAO Aventis Pharma	Russia	100
Sanofi-Aventis Vostok	Russia	51
Zentiva Pharma o.o.o.	Russia	100
Sanofi-Aventis Pharma Slovakia s.r.o.	Slovakia	100
Zentiva International a.s.	Slovakia	100
Sanofi-Aventis AB	Sweden	100
Sanofi SA-(Sanofi AG)	Switzerland	100
Sanofi-Aventis (Suisse) SA	Switzerland	100
Sanofi-Aventis Ilaclari Limited Sirketi	Turkey	100
Winthrop Ilac Anonim Sirketi	Turkey	100
Sanofi-Synthélabo Ilac AS	Turkey	100
Sanofi-Synthélabo BMS ADI Ortakligi partnership <sup>(1)</sup>	Turkey	50.1
Zentiva Saglik Urunleri San.Ve Tic.A.S.	Turkey	100
Limited Liability Company Sanofi-Aventis Ukraine	Ukraine	100

<sup>(1)</sup> Partnership with Bristol-Myers Squibb (see Note C.1.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

		<b>Financial interest</b>
<i>United States</i>		<i>%</i>
Armour Pharmaceutical Company	United States	100
Aventis Inc.	United States	100
Aventisub Inc.	United States	100
Aventis Holdings Inc.	United States	100
Aventis Pharmaceuticals Inc.	United States	100
BiPar Sciences Inc	United States	100
Carderm Capital L.P.	United States	100
Chattem, Inc.	United States	100
Merial, Inc.	United States	100
Merial Select, Inc.	United States	100
Sanofi-Aventis US Inc.	United States	100
Sanofi-Aventis US LLC.	United States	100
Sanofi Pasteur Biologics Co.	United States	100
Sanofi Pasteur Inc.	United States	100
Sanofi-Synthélabo Inc.	United States	100
Signal Investment & Management Co.	United States	100
SunDex, LLC	United States	100
TargeGen, Inc.	United States	100
Sanofi Pasteur VaxDesign Corporation	United States	100
BMP Sunstone Corporation	United States	100
Genzyme Corporation	United States	100
Sanofi-Topaz, Inc.	United States	100
Vaxserve Inc.	United States	100

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

		<b>Financial interest</b>
		<b>%</b>
<i>Other countries</i>		
sanofi-aventis South Africa (Proprietary) Ltd	South Africa	100
Winthrop Pharmaceuticals (Proprietary) Limited	South Africa	100
Winthrop Pharma Saïdal S.P.A.	Algeria	70
Sanofi-Aventis Algérie	Algeria	100
Merial Argentina S.A.	Argentina	100
Sanofi-Aventis Argentina S.A.	Argentina	100
Quimica Medical S.A.	Argentina	100
Sanofi-Aventis Australia Pty Limited	Australia	100
Sanofi-Aventis Healthcare Holdings Pty Ltd	Australia	100
Sanofi-Aventis Healthcare Pty Ltd	Australia	100
Bullivant s Natural Health Products (International) Pty Ltd	Australia	100
Bullivant s Natural Health Products Pty Ltd	Australia	100
Cenovis Pty Ltd	Australia	100
MCP Direct Pty Ltd	Australia	100
Carlson Health Pty Ltd	Australia	100
Merial Australia (PTY) LTD	Australia	100
Merial Saude Animal Ltda	Brazil	100
Sanofi-Aventis Comercial e Logistica Ltda	Brazil	100
Sanofi-Aventis Farmaceutica Ltda	Brazil	100
Medley Comercial e Logistica Ltda	Brazil	100
Medley S.A. Industria Farmaceutica Ltda	Brazil	100
Merial Canada, Inc.	Canada	100
Sanofi Pasteur Limited	Canada	100
Canderm General Partnership	Canada	100
Sanofi-Aventis Canada Inc.	Canada	100
Sanofi Santé Grand Public Inc.	Canada	100
Chattem Canada ULC	Canada	100
Chattem Canada	Canada	100
Sanofi-Aventis de Chile SA	Chile	100
Sanofi (China) Investment Co., Ltd.	China	100
Sanofi-Aventis Pharma Beijing Co. Ltd	China	100
Sanofi-Aventis (Hangzhou) Pharmaceuticals Co. Ltd	China	100
Shenzhen Sanofi Pasteur Biological Products Co. Ltd	China	100
Hangzhou Sanofi Minsheng Consumer Healthcare Co. Ltd	China	60
Merial Animal Health Co. Ltd	China	99
Sunstone (TangShan) Pharmaceutical Co., Ltd.	China	100
Winthrop Pharmaceuticals de Colombia SA	Colombia	100
Sanofi-Aventis de Colombia SA	Colombia	100
Sanofi-Aventis Korea Co. Ltd	Korea	91
Sanofi-Aventis Gulf F.Z.E.	United Arab Emirates	100
Sanofi-Aventis Egypt SAE	Egypt	99.8
Sanofi-Aventis del Ecuador S.A.	Ecuador	100
Sanofi-Aventis de Guatemala S.A.	Guatemala	100
Sunstone China Limited	Hong Kong	100
Sanofi-Aventis Hong Kong Limited	Hong Kong	100
Sanofi-Synthelabo (India) Limited	India	100

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

		<b>Financial interest</b>
		<b>%</b>
<i>Other countries</i>		
Aventis Pharma Ltd	India	60.4
Shantha Biotechnics Limited	India	96.4
PT Sanofi-Aventis Indonesia	Indonesia	100
PT Aventis Pharma	Indonesia	75
Sanofi-Aventis K.K.	Japan	100
Sanofi-Aventis Meiji Pharmaceuticals Co Ltd	Japan	51
Sanofi-Aventis Yamanouchi Pharmaceutical Inc.	Japan	51
Sanofi Pasteur K.K.	Japan	100
Merial Japan Limited	Japan	80
Winthrop Pharmaceuticals (Malaysia) SDN.BHD	Malaysia	100
Sanofi-Aventis (Malaysia) SDN.BHD	Malaysia	100
Maphar	Morocco	80.6
Sanofi-Aventis (Maroc)	Morocco	100
Merial México S.A. de C.V.	Mexico	100
Sanofi Pasteur S.A. de C.V.	Mexico	100
Sanofi-Aventis de Mexico SA de CV	Mexico	100
Sanofi-Aventis Winthrop SA de CV	Mexico	100
Mexico Winthrop Pharmaceuticals de Mexico SA de CV	Mexico	100
Laboratorios Kendrick S.A.	Mexico	100
Sanofi-Aventis Pakistan Ltd	Pakistan	52.9
Sanofi-Aventis de Panama S.A.	Panama	100
Sanofi-Aventis Latin America SA	Panama	100
Sanofi-Aventis del Peru S.A.	Peru	100
Chattem Peru S.R.L.	Peru	100
Sanofi-Aventis Philippines Inc.	Philippines	100
Sanofi-Aventis de la Rep. Dominicana S.A.	Dominican Rep.	100
Aventis Pharma (Manufacturing) Pte. Ltd	Singapore	100
Sanofi-Aventis Singapore Pte. Ltd	Singapore	100
Sanofi-Aventis Taiwan Co. Ltd	Taiwan	100
Sanofi-Synthélabo (Thailand) Ltd	Thailand	100
Sanofi-Aventis (Thailand) Ltd	Thailand	100
Sanofi-Aventis Pharma Tunisie	Tunisia	100
Winthrop Pharma Tunisie	Tunisia	100
Sanofi-Aventis de Venezuela SA	Venezuela	100
Sanofi-Synthélabo Vietnam Pharmaceutical Shareholding Co	Vietnam	70
Sanofi-Aventis Vietnam Co. Ltd	Vietnam	100

The Group has also consolidated Merial and its subsidiaries since September 18, 2009, the date on which control was acquired (see Note D.8.1.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****F.2. Principal associates and joint ventures**

		<b>Financial interest</b>
		<b>%</b>
InfraServ GmbH & Co Höchst KG	Germany	31.2
Handok Pharmaceuticals Co. Ltd	Korea	50
Bristol-Myers Squibb / Sanofi Canada Partnership	Canada	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Holding Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Partnership Puerto Rico	United States	49.9
Bristol-Myers Squibb / Sanofi-Synthélabo Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi-Synthélabo Puerto Rico Partnership	United States	49.9
Sanofi Pasteur MSD S.N.C.	France	50

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